

**Technology and Equipment  
Committee Meeting**

**August 29, 2007**

**Positron Emission Tomography  
(PET) Scanner  
Material**

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**Positron Emission Tomography  
(PET) Scanner  
Material**

**Material Related To**

**PET Petition: The Presbyterian Hospital**

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PETITION TO THE NORTH CAROLINA STATE HEALTH COORDINATING  
COUNCIL REGARDING THE NEED DETERMINATION FOR POSITRON  
EMISSION TOMOGRAPHY SCANNERS IN THE 2008 STATE MEDICAL  
FACILITIES PLAN

The Presbyterian Hospital ("Presbyterian") hereby petitions the North Carolina State Health Coordinating Council ("SHCC"), to adjust the need determination contained in the Proposed 2008 State Medical Facilities Plan ("SMFP") at Table 9M, page 122, to show a need determination for a fixed dedicated positron emission tomography ("PET") scanner in Health Service Area ("HSA") III.

DFS Health Planning  
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JUL 26 2007

Identification of Petitioner

MEDICAL FACILITIES  
PLANNING SECTION

Presbyterian is a non-profit corporation operating a full service hospital in Charlotte with 463 licensed acute care beds. Presbyterian offers a comprehensive cancer program with two linear accelerators<sup>1</sup> currently in operation. Presbyterian is planning to deploy a third linear accelerator in 2008 in a satellite location in southern Mecklenburg County at Ballantyne.<sup>2</sup> As shown in the Proposed 2008 SMFP, Presbyterian provided 16,659 radiation oncology procedures in the most recent annual period for which information is available. See Exhibit A. As measured by the total ESTV-weighted radiation therapy procedures for FFY 2006 reported in the 2007 Presbyterian Hospital Licensure Renewal application and in the proposed 2008 SMFP, Presbyterian Hospital is the tenth busiest cancer treatment program in the state (64 total facilities) and treats many breast cancer cases. See Exhibit B.

<sup>1</sup> Two linear accelerators are currently in operation at Presbyterian Hospital. Two additional linear accelerators are refurbished units owned by Presbyterian Hospital, but not in operation at this time. See Exhibit A (2007 TPH LRA, Pages 11-12).

<sup>2</sup> Pursuant to settlement in Project I.D. # F-7518-06.

Presbyterian may be contacted about this Petition directly or through its counsel, at the following addresses:

Presbyterian Healthcare  
Fred Hargett, Senior Vice President  
Financial Planning & Analysis  
200 Hawthorne Lane  
Charlotte, NC 28204  
Telephone: (704) 384-4000  
[fmhargett@novanthealth.org](mailto:fmhargett@novanthealth.org)

Nelson Mullins Riley & Scarborough LLP  
Noah H. Huffstetler, III  
Counsel for Petitioner  
4140 Parklake Avenue, Suite 200  
Raleigh, NC 27612  
Telephone: (919) 877-3801  
[noah.huffstetler@nelsonmullins.com](mailto:noah.huffstetler@nelsonmullins.com)

### Reason for Proposed Adjustment

On page 121, the Proposed 2008 SMFP provides in pertinent part:

One additional fixed dedicated PET scanner is needed for each existing fixed PET scanner that was utilized at or above 80% of capacity during the twelve month period reflected in the owner's or operator's 2007 Hospital Licensure Renewal Application on file with the N.C. Division of Facility Services. For the purposes of this determination, the annual capacity of a fixed dedicated PET scanner is  $(2,600 \times .80 = 2,080)$  procedures....

Applying this methodology, Table 9M on page 122 of the Proposed 2008 SMFP shows no need for an additional fixed PET scanner in HSA III, in which Presbyterian is located. For the period covered by its 2007 annual license renewal application, the twelve months ending September 30, 2006, the utilization rate for Presbyterian's PET scanner was 1,988 procedures, or 76.46% of capacity. This utilization of Presbyterian's equipment, based on PET scans per scanner, ranks third among the twenty-two facilities in North Carolina with fixed PET scanners, but is slightly below the 80% figure<sup>3</sup> which would trigger the need for an additional PET scanner in HSA III using the standard methodology. See Exhibit C.

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<sup>3</sup> The 80% figure to trigger need for the next new PET scanner is 2,080 PET scans per year. The Presbyterian Hospital Pet scan volume for FFY 06 is only 92 PET procedures shy of that volume.

However, the data set forth in Exhibit F to this Petition shows that the utilization of Presbyterian's PET scanner continues to grow rapidly, and that its current utilization actually exceeds that necessary to justify an additional PET scanner. As shown Exhibit F, for the 12 months ending November 30, 2006--- just two more months beyond the data reported in the 2008 SMFP for FFY 2006<sup>4</sup>-- Presbyterian's PET scanner was utilized for 2,095 procedures<sup>5</sup>, or 81% of its capacity. Thus, by applying the standard methodology utilized in the Proposed 2008 SMFP to information that is more current by only two months, a need for an additional PET scanner within HSA III is easily established. In the alternative, for the 12 months ending December 31, 2006--- one quarter beyond the data reported in the 2008 SMFP for FFY 2006--- Presbyterian's PET scanner was utilized for 2,128 procedures, or 102% of its capacity. See Exhibit F. Thus, again by applying the standard methodology utilized in the Proposed 2008 SMFP to information that is more current by only three months, a need for an additional PET scanner within HSA III is easily established.

It is important to also note that the TPH average PET scans per month in each fiscal year of operation have increased steadily since the Presbyterian Hospital PET scanner began operation in October 2004:

- FFY 2005 TPH Average PET scans per month: 140.4
- FFY 2006 TPH Average PET scans per month: 165.7
- FFY 2007<sup>6</sup> TPH Average PET scans per month: 193.8

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<sup>4</sup> FFY 2006 as reported in Table 9K in the proposed 2008 SMFP (page 119) is the period 10/1/05-9/30/06. See Exhibit C.

<sup>5</sup> The Presbyterian Hospital PET scanner volumes for the 12-month period December 1, 2006 through November 2006 are 2,095 PET procedures, which is 15 PET procedures beyond the 2,080 PET scans required to trigger need for a new scanner in HSA III.

<sup>6</sup> Based on annualized FFY 2007 project total volumes of 2,325 PET scans per year (using 8 months of actual data).

The Presbyterian Hospital average PET scans per month for each Fiscal Year (the reporting year for the SMFPs) have increased almost 40% from the time the TPH PET scanner became operational in October 2004 until eight months into FFY 2007<sup>7</sup>.

The growth in Presbyterian's PET scanning services is likely not only to continue, but to accelerate. The discussion of PET utilization contained at pages 116-118 of the Proposed 2008 SMFP recognized "the steady growth in the number of clinical studies in which the Centers for Medicare and Medicaid Services ("CMS") authorized reimbursement for PET scanning," and concludes that "the clinical use of PET scanning is increasing rapidly, and the new applications involve the diagnosis of cancer." As shown on Table 9G at pages 108-09 of the Proposed 2008 SMFP, Presbyterian's radiation oncology service ranks tenth among the sixty-four facilities providing that service in North Carolina in the number of procedures performed. Given the robust and growing cancer treatment programs offered by Presbyterian, and the rapidly increasing number of types of cancer for which PET scanning is useful, it is clear that Presbyterian's PET utilization is likely to grow even more quickly in the coming years. See the information on CMS's National Oncologic PET Registry (NOPR) attached as Exhibit G, the June 2007 recommendations of the National Comprehensive Cancer Networks (NCCN) Task Force regarding the use of PET and PET/CT in the evaluation and management of certain types of cancer, attached as Exhibit D, and "Advance for Imaging & Oncology Administrators," noting that recent years, FDG-18-based PET scans have become the main source of biological imaging information for Radiation Therapy, outpacing MRI, CT, and ultrasound, attached as Exhibit H. This is further substantiated

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<sup>7</sup> Calculation:  $(193.8 - 140.4 \text{ average scans mo}) / 140.4 \text{ scans per month} = 38\% \text{ increase from FFY 2004 to FFY 2007 YTD in average number of monthly PET scans at Presbyterian Hospital.}$

by the letter of Dr. Robert Quarles, Mecklenburg Radiology Associates, Medical Director for Nuclear Medicine and PET, Radiology Department, Presbyterian Hospital, which is attached as Exhibit E to this Petition.

For all of the foregoing reasons, an additional PET scanner should be determined to be needed in HSA III in the 2008 SMFP, and Presbyterian and any other qualified applicant should be permitted to apply for a certificate of need to acquire that additional PET scanner.

Presbyterian also concurs with the Forsyth Medical Center PET Comments presented at the July 20<sup>th</sup>, 2007 public hearing for the proposed 2008 SMFP that any proposal to change the statewide methodology for making PET scanner need determinations<sup>8</sup> should only be considered in accordance with the established State Health Planning process for inclusion in the 2009 SMFP.

*File: PETPetitionPresby08SMFPtoSHCC,07.25.07.FINAL.doc*

<sup>8</sup> At the May 2007 meeting of the SHCC's Medical Equipment and Technology Committee, it was suggested that the annual volume threshold to trigger need for the next new fixed PET CT scanner should be increased from the current 2,080 to 2,500 annual PET procedures as early as the 2008 SMFP. Further discussion of this issue has been put on the Agenda for a DFS Health Facilities Planning Section-sponsored Discussion Group meeting set for August 15, 2007, a date that is after the close of the public hearing comment period on the 2008 proposed SMFP.

2007 Renewal Application for Hospital:  
Presbyterian Hospital

License No: H0010  
 Facility ID: 943501

All responses should pertain to October 1, 2005 through September 30, 2006. If otherwise, indicate the actual reporting period used on Page 3 of this document.

## 12. Radiation Oncology Treatment Data *continued*

a.	Number of unduplicated <u>patients</u> who receive a course of radiation oncology treatments (patients shall be counted more than once if they receive additional courses of treatment)	541
b.	Total number of Linear Accelerator(s) *	4
c.	Number of Linear Accelerators configured for stereotactic radiosurgery	0

12. Telemedicine \* One linac was the subject of a replacement equipment con application in March, 2006.

a. Does your facility utilize telemedicine to have images read at another facility? no

b. Does your facility read telemedicine images? yes

## 13. Additional Services:

a) Check if Service(s) is provided:

	Check		Check
1. Cardiac Rehab Program (Outpatient)	<input checked="" type="checkbox"/>	5. Rehabilitation Outpatient Unit	<input type="checkbox"/>
2. Chemotherapy	<input checked="" type="checkbox"/>	6. Podiatric Services	<input type="checkbox"/>
3. Clinical Psychology Services	<input checked="" type="checkbox"/>	7. Genetic Counseling Service	<input checked="" type="checkbox"/>
4. Dental Services	<input type="checkbox"/>	8. Acute Dialysis	<input checked="" type="checkbox"/>

Number of Acute Dialysis Stations 10

b) Hospice Inpatient Unit Data:

Hospital-based hospice units with licensed hospice beds. List each county served and report all patients by county of residence. Use each patient's age on the admission day to the Licensed Hospice Inpatient Facility. For age categories count each inpatient client only once.

County of Residence	Age 0-17	Age 18-40	Age 41-59	Age 60-64	Age 65-74	Age 75-84	Age 85+	Total Patients Served	Total Days of Care	Deaths
Out of State										
Total All Ages	0	10	74	28	84	156	113	465	2,215	326

Revised 08/2006

\* In June 2005 TPH purchased and now owns 2 additional linear accelerators; these linear accelerators are not operational at this time. Page 15



2007 Renewal Application for Hospital:  
Presbyterian Hospital

License No: H0010  
 Facility ID: 943581

All responses should pertain to October 1, 2005 through September 30, 2006. If otherwise, indicate the actual reporting period used on Page 3 of this document.

### 11. Radiation Oncology Treatment Data

CPT Code	Description	Number of Procedures	ESTV/ Procedures Under ACR	Total ACR ESTVs	
<b>Simple Treatment Delivery:</b>					
77401	Radiation treatment delivery	140	1.00	140	
77402	Radiation treatment delivery (<=5 MeV)	0	1.00		
77403	Radiation treatment delivery (6-10 MeV)	161	1.00	161	
77404	Radiation treatment delivery (11-19 MeV)	84	1.00	84	
77406	Radiation treatment delivery (>=20 MeV)	0	1.00		
<b>Intermediate Treatment Delivery:</b>					
77407	Radiation treatment delivery (<=5 MeV)	0	1.00		
77408	Radiation treatment delivery (6-10 MeV)	15	1.00	15	
77409	Radiation treatment delivery (11-19 MeV)	2	1.00	2	
77411	Radiation treatment delivery (>=20 MeV)	0	1.00		
<b>Complex Treatment Delivery:</b>					
77412	Radiation treatment delivery (<=5 MeV)	0	1.00		
77413	Radiation treatment delivery (6-10 MeV)	4,270	1.00	4,270	
77414	Radiation treatment delivery (11-19 MeV)	5,029	1.00	5,029	
77416	Radiation treatment delivery (>= 20 MeV)	35	1.00	35	
	<b>Sub-Total</b>	<b>9,736</b>		<b>9,736</b>	

For the increased time required for special techniques, ESTV values are indicated below:

77417	Additional field check radiographs	6425	.50	3,213	
77418	Intensity modulated radiation treatment (IMRT) delivery	3685	1.00	3,685	
77432	Stereotactic radiosurg. treatment mgmt Linear Accelerator	0	3.00		
77432	Stereotactic radiosurg. Treatment mgmt. Gamma Knife	0	3.00		
	Total body irradiation	0	2.50		
	Hemibody irradiation	0	2.00		
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linac)	0	10.00		
	Neutron and proton radiation therapy	0	2.00		
	Limb salvage irradiation	0	1.00		
	Pediatric Patient under anesthesia	3	1.50	4.5	
	<b>Sub-Total</b>	<b>10,113</b>		<b>6,902.5</b>	
	<b>TOTALS:</b>	<b>19,849</b>		<b>16,638.5</b>	

Note: For special techniques, list procedures under both the treatment delivery and the special techniques sections.

**Table 9G: Hospital and Free-Standing Linear Accelerators  
and Radiation Oncology Procedures (see note at bottom of table)**

Facility Name	Service Area #	County	LIN ACC	PROCEDURES (ESTVs)	
				2005-2006	Average per Unit
Harris Regional Hospital, Inc.-Mtn Trace	1	Jackson	1	4,503	4,503
NC Radiation Therapy - Franklin	1	Macon	1	2,277	2,277
Mission Hospitals (S) (b)	2	Buncombe	3	20,766	6,922
NC Radiation Therapy - Asheville	2	Buncombe	2	7,012	3,506
NC Radiation Therapy - Clyde	2	Haywood	1	4,359	4,359
NC Radiation Therapy - Marion	2	McDowell	1	2,534	2,534
Watauga Hospital	3	Watauga	1	4,491	4,491
Margaret Pardee Mem. Hospital	4	Henderson	1	6,591	6,591
NC Radiation Therapy - Brevard	4	Transylvania	1	1,709	1,709
NC Rad. Therapy - Hendersonville	4	Henderson	1	645	645
Catawba Valley Medical Center	5	Catawba	2	18,008	9,004
Frye Regional Medical Center	5	Catawba	1	NA	NA
Grace Hospital, Inc.	5	Burke	1	NR	NR
Valdese General	5	Burke	1	6,082	6,082
Caldwell Memorial Hospital, Inc.	5	Caldwell	1	1,056	1,056
Cleveland Regional	6	Cleveland	1	6,989	6,989
Gaston Memorial Hospital (h)	6	Gaston	3	11,761	3,920
NC Radiation Therapy - Forest City	6	Rutherford	1	4,656	4,656
2006 SMFP Need Determination	7		1		
Carolinas Medical Center (S)	7	Mecklenburg	3	14,128	4,709
CMC-Union Reg. Medical Center (i)	7	Union	1	8,428	8,428
Matthews Radiation Oncology	7	Mecklenburg	1	10,803	10,803
Presbyterian Hospital	7	Mecklenburg	4	16,659	4,165
University Radiation Oncology	7	Mecklenburg	1	7,289	7,289
Iredell Memorial	8	Iredell	2	6,834	3,417
Lake Norman Radiation Oncology Ct	8	Iredell	1	4,641	5,525
Rowan Regional Medical Center	8	Rowan	1	5,519	5,519
NorthEast Medical Center	9	Cabarrus	2	13,009	6,505
Stanly Regional Medical Center	9	Stanly	1	4,427	4,427
Forsyth Memorial Hospital	10	Forsyth	4	28,435	7,109
Hugh Chatham Memorial Hospital (d)	10	Surry	1	3,911	3,911
N. C. Baptist Hospitals (S)	10	Forsyth	4	20,251	5,063
2006 SMFP Need Determination	11	Davidson	1		
High Point Regional Health System	12	Guilford	2	9,344	4,672
Morehead Memorial Hospital	12	Rockingham	1	5,972	5,972
Moses Cone Health System	12	Guilford	4	28,362	7,091
Randolph Cancer Center (m)	13	Randolph	1	NA	NA
UNC Hospitals (S)	14	Orange	4	22,224	5,556

**Table 9G: Hospital and Free-Standing Linear Accelerators  
and Radiation Oncology Procedures** (see note at bottom of table)

Facility Name	Service Area #	County	LIN ACC	PROCEDURES (ESTVs)	
				2005-2006	Average per Unit
Alamance Regional Medical Center (j)	15	Alamance	2	7,991	3,996
Duke University Hospital (S)	16	Durham	5	(36,634)	7,327
Durham Regional Hospital	16	Durham	1	6,128	6,128
Maria Parham Hospital (e)	16	Vance	1	4,833	4,833
FirstHealth Moore Regional	17	Moore	2	(23,764)	11,882
Scotland Memorial Hospital (1)	17	Scotland	1	4,122	4,122
Cape Fear Valley Medical Center (a)	18	Cumberland	4	(27,631)	6,908
Southeastern Regional Medical Center	18	Robeson	1	9,484	9,484
New Hanover Radiation Oncology	19	New Hanover	2	(15,156)	7,578
New Hanover Regional Med Ctr	19	New Hanover	1	7,599	7,599
South Atlantic Radiation Oncology, LLC (c)	19	Brunswick	1	NA	0
2007 SMFP Need Determination	20		1		
Cancer Ctrs of NC - Raleigh Hematology	20	Wake	1	8,924	8,924
Duke Raleigh Hospital	20	Wake	1	7,323	7,323
Rex Hospital	20	Wake	4	16,184	4,046
Wake Radiology Oncology Services	20	Wake	1	5,960	5,960
Triangle Radiation Oncology Services	21	Johnston	1	2,648	1,093
2006 SMFP Need Determination	21	Johnston	1		
Lenoir Memorial	22	Lenoir	1	6,147	6,147
Wayne Radiation Oncology Center	22	Wayne	1	6,952	6,952
Carteret General (g)	23	Carteret	1	4,015	4,015
Craven Regional Med Ctr	23	Craven	2	12,415	6,208
2006 SMFP Need Determination	24	Onslow	1		
Nash Day Hospital	25	Nash	2	7,905	3,953
Roanoke Valley Cancer Center	25	Halifax	1	3,208	3,208
Wilson Memorial Hospital	25	Wilson	1	4,413	4,413
Ahoskie Cancer Center	26	Hertford	1	3,173	3,173
Carolina Radiation Medicine, P.A. (f) (S)	26	Pitt	1	8,206	8,206
Pitt County Memorial Hospital (S)	26	Pitt	3	16,013	5,338
Albemarle Hospital	27	Pasquotank	1	4,403	4,403
Outer Banks Cancer Center	27	Dare	1	4,977	4,977
<b>TOTALS (64 Facilities)</b>			<b>112</b>	<b>579,883</b>	<b>5,178</b>

**Note:** The above inventory of linear accelerators is subject to change if it is determined that any of the listed equipment was not acquired in accordance with N.C. G. S. 131E-175, et seq, prior to August 26, 2005.  
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## Proposed 2008 SMFP

Table 9K: PET Scanner Utilization of Existing Fixed Dedicated Scanners

Center	Procedures				HSA	Inventory	Utilization Rate Year 2006 Procedures / 2600 as Capacity	Need Determination by Criteria - 80% of Present Capacity
	2002- 2003	2003- 2004	2004- 2005	2005- 2006				
Mission Hospitals (f)		644	875	1003	I	1	38.58%	
Catawba Valley/ Frye Reg. (j)			848	1258	I	1	48.38%	
N.C. Baptist Hospitals	1817	1797	1266	1477	II	1	56.81%	
Moses Cone Health System (o)			1352	1760	II	1	67.69%	
Forsyth Medical Center (p)		130	1579	2412	II	1	92.96%	1
High Point Regional (r)		179	356	574	II	1	22.08%	
Alamance Reg. Medical Ctr. (u)				374	II	1	14.38%	mobile procedures
Carolinas Med Center(a),(k)	2414	2908	3049	3635	III	2	69.90%	1818/Scanner
Gaston Mem. / CTS Summit (m)		172	700	846	III	1	32.54%	
NorthEast Medical Center (n)		330	481	615	III	1	23.65%	
The Presbyterian Hospital (q)			1544	1988	III	1	76.46%	
Iredell Memorial Hospital (t)				NA	III	1	NA	
Duke Univ. Hospital (d)	3259	3135	3091	3596	IV	2	69.15%	1798/Scanner
UNC Hospitals (b)	1230	1389	1144	1386	IV	2	26.65%	643/Scanner
Rex Hospital (e)	407	1116	1544	1913	IV	1	73.58%	
Wake PET Services, Wake Radiology Oncology, Wake Radiology, WakeMed (s)				NA	IV	1		
New Hanover Reg. Med. (g)			582	755	V	1	29.04%	
Cape Fear Valley Medical Ctr. (h)		629	1218	2069	V	1	79.58%	0
First Imaging of the Carolinas (i)		351	529	550	V	1	21.15%	
Pitt Co. Memorial (c)		418	393	832	VI	1	32.00%	
Craven Reg. Medical (l)			719	831	VI	1	31.96%	
Nash General Hospital (u)				336	VI	1	12.92%	mobile procedures
<b>TOTAL</b>	<b>9,127</b>	<b>13,198</b>	<b>21,270</b>	<b>28,215</b>		<b>25</b>		<b>1</b>

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NA Not Applicable for time period ending September 30, 2006.

- (a) Approved for additional scanner in November 2001.  
 (b) Approved for scanner in June 2000 and additional scanner under Policy AC-3 in November 2005.  
 (c) Approved for scanner in August 2001.  
 (d) Approved for additional scanner under Policy AC-3 in September 2002.  
 (e) Approved for scanner in September 2002.  
 (f) Approved for scanner in January 2003.  
 (g) Operational in October 2004.  
 (h) Approved for scanner in August 2003.  
 (i) Approved for scanner in August 2003.  
 (j) Approved for scanner in July 2003.  
 (k) Approved for replacement of 1 scanner in June 2003.
- (l) Approved for scanner in October 2003.  
 (m) Approved for scanner in December 2003.  
 (n) Approved for scanner in December 2003.  
 (o) Operational in October 2004.  
 (p) Approved for scanner in June 2004.  
 (q) Approved for scanner in June 2004.  
 (r) Approved for scanner in January 2005.  
 (s) Approved for scanner in November 2005.  
 (t) Approved for scanner in January 2007.  
 (u) Approved for scanner in April 2007.  
 (v) Approved for scanner in May 2007.

Exhibit D



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## NCCN Task Force Develops Clinical Recommendations for PET in Cancer Evaluation and Management

JENKINTOWN, Pa., June 5, 2007 — The National Comprehensive Cancer Network (NCCN) will publish a special report entitled *NCCN Task Force Report: Positron Emission Tomography (PET)/Computed Tomography (CT) Scanning in Cancer* as a supplement to the May issue of its journal. The report is the work of a Task Force convened by NCCN to develop clinical recommendations for the use of PET and PET/CT in the evaluation and management of certain types of cancer.

PET is a non-invasive imaging technique used frequently to detect cancer and assess the effects of cancer treatment. However, PET is more costly than other traditional types of imaging. The report, to be published in the *Journal of the National Comprehensive Cancer Network (JNCCN)*, addresses this challenge and offers recommendations as to when PET is appropriate and most useful.

The Task Force, made up of expert radiologists, surgeons, radiation oncologists and medical oncologists from NCCN Member Institutions, studied existing data to create their recommendations. According to the Task Force Report, "The role of PET or PET/CT scans in oncology is rapidly evolving, with well-defined roles in the common malignancies of breast, lung, colorectal cancer, and lymphoma." In response to concerns about economics, the report suggests that PET can sometimes reduce costs. For example, PET scans can be cost-saving when the results are used to prevent unnecessary surgeries.

"The role of PET or PET/CT scans in oncology is rapidly evolving," said Donald Podoloff, MD, chair of the Task Force and head of the Division of Diagnostic Imaging at The University of Texas M. D. Anderson Cancer Center. "With the collective expertise of this Task Force, we were able to make recommendations for appropriate use of this technology. As a result, we hope that PET and PET/CT will demonstrate its cost effectiveness and value to patients, physicians and managed care providers. The rapid acceptance of PET/CT is a testimony to the unique, noninvasive and important information it provides to oncologists as they manage their patients."

The report will be published as a supplement to *JNCCN*, a nationally recognized, peer-reviewed medical journal received by more than 21,000 oncologists and other cancer care professionals across the United States.

For questions about NCCN or for interview information, please contact Thomas Mitchell at 215 690 0245.

### About the National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN), a not-for-profit alliance of 21 of the world's leading cancer centers, is dedicated to improving the quality and effectiveness of care provided to patients with cancer. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. As the arbiter of high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers. The primary goal of all NCCN initiatives is to improve the quality, effectiveness, and efficiency of oncology practice so patients can live better lives.

### The NCCN Member Institutions are:

- ▶ City of Hope
- ▶ Dana-Farber/Brigham and Women's Cancer Center

- Massachusetts General Hospital Cancer Center
- ▶ Duke Comprehensive Cancer Center
- ▶ Fox Chase Cancer Center
- ▶ Huntsman Cancer Institute at the University of Utah
- ▶ Fred Hutchinson Cancer Research Center / Seattle Cancer Care Alliance
- ▶ Arthur G. James Cancer Hospital & Richard J. Solove Research Institute at The Ohio State University
- ▶ The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
- ▶ Robert H. Lurie Comprehensive Cancer Center of Northwestern University
- ▶ Memorial Sloan-Kettering Cancer Center
- ▶ H. Lee Moffitt Cancer Center & Research Institute at the University of South Florida
- ▶ Roswell Park Cancer Institute
- ▶ Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine
- ▶ St. Jude Children's Research Hospital / University of Tennessee Cancer Institute
- ▶ Stanford Comprehensive Cancer Center
- ▶ University of Alabama at Birmingham Comprehensive Cancer Center
- ▶ UCSF Comprehensive Cancer Center
- ▶ University of Michigan Comprehensive Cancer Center
- ▶ UNMC Eppley Cancer Center at The Nebraska Medical Center
- ▶ The University of Texas M. D. Anderson Cancer Center
- ▶ Vanderbilt-Ingram Cancer Center

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# Presbyterian HOSPITAL

*Remarkable People. Remarkable Medicine.*

July 25, 2007

Chris Ullrich, M.D., Chair  
Medical Equipment and Technology Committee  
State Health Coordinating Council  
701 Barbour Drive  
Raleigh, NC 27603

Subject: Petition to the State Health Coordinating Council Regarding the Need Determination for One New PET Scanner for HSA III in the Proposed 2008 State Medical Facilities Plan

Dear Dr. Ullrich:

I support the amendment of the proposed 2008 State Medical Facilities Plan, for the addition of Need Determination for one new fixed dedicated positron emission tomography (PET) scanner in Health Service Area (HSA) III. An additional scanner is needed as PET services will clearly continue to grow and Presbyterian Hospital's PET scanner's FFY 2006 PET procedures are only 4% shy<sup>1</sup> of the threshold for a new PET scanner set forth in the proposed 2008 SMFP.

The Presbyterian Hospital began offering PET services in October 2004 and since then we have completed almost 5,000 exams<sup>2</sup>. As shown below, the average number of exams per month has increased steadily and is currently almost 195 per month. Currently, well over 95% of these exams have been completed on oncology patients. The Presbyterian Hospital (TPH) Cancer Center is one of the top ten busiest cancer centers in the state of the 64 North Carolina cancer treatment centers, when measured by the number of ESTV radiation therapy treatments offered during FFY 2006 as reported in the proposed 2008 SMFP.<sup>3</sup> TPH will deploy a third linear accelerator in 2008 in a satellite location in southern Mecklenburg County at Ballantyne. TPH's Cancer program provides care to a large number of breast cancer cases, which is in large measure related to the subspecialty radiologists, the imaging equipment (including PET and MRI), the cancer center physicians and surgeons and the linear accelerators and other treatment options. Thus, a second PET scanner will become necessary to keep up with the growing demand from cancer physicians and their patients.

With regard to PET growth, the National Oncologic PET Registry (NOPR) was established in 2005 to respond to a proposal by the Centers for Medicare and Medicaid Services (CMS) to expand coverage for PET with F-18 fluorodeoxyglucose (<sup>18</sup>FDG) to include cancers and indications not presently eligible for Medicare reimbursement. Prior to May 2006 when the NOPR began registering patients to capture data on additional diagnostic indications for the use of PET scans, CMS paid for PET scans for only nine types of cancer. See attached Table from the NOPR website (<http://www.cancerpetregistry.org>) showing the types of PET scans that are already covered for Medicare reimbursement (designated with a "C") and the types of cancers and indications for which Medicare reimbursement is available thorough the NOPR (designated with a "checkmark") if the patient's referring physician and the provider submit data to the clinical registry to assess the impact of PET diagnostic information on cancer patient management. See Exhibit E attached to The Presbyterian Hospital Petition. Sponsored by the Academy of

<sup>1</sup> Calculation:  $(2,080 \text{ PET px threshold } 08 \text{ SMFP} - 1,988 \text{ TPH PET px FFY } 06) / 2,080 = 4.4\%$

<sup>2</sup> Calculation of Presbyterian Hospital PET scan volumes from October 2004 through May 2007: (FFY 2005 at 1,544) + (FFY 2006 at 1,988) + (FFY 07 Year to Date/8 months at 1,550 and FFY 2007 annualized at 2,325). Thus total PET and PET/CT exams at Presbyterian Hospital for Oct 2004 – May 2007 = 5,082 (1544 + 1988 + 1550).

<sup>3</sup> Based on E STV-weighted radiation therapy procedures report in the Proposed 2008 SMFP: (1) Duke at 36,634; (2) FMC at 28,435; (3) Moses Cone Health System at 28,362; \*4) Cape Fear Valley Medical Center at 27,631; (5) First Health Moore Regional at 23,764; (6) UNC Hospitals at 22, 224; (7) Mission Hospitals at 20,776; (8) NCBH at 20,251; (9) Catawba Valley Medical Center at 20,766; (10) The Presbyterian Hospital at 16,659.

# Presbyterian HOSPITAL

*Remarkable People. Remarkable Medicine.*

Molecular Imaging and managed by the American College of Radiology (ACR) through the ACR Imaging Network, the NOPR is implementing this registry for CMS. Considering the impact of the NOPR, PET will surely continue to grow as the CMS begins to cover for more cancers, the diagnosis, initial staging, treatment monitoring during therapy (chemotherapy, radiation therapy, or combined modality therapy) and re-staging after completion of therapy and detection of suspected recurrence.

Practically, the hours of operation for a PET/CT scanner at facilities such as PH are more limited than suggested by the state. Unlike CT or MRI that must operate 66 hours per week as per 10A NCAC 14C.2302(k) or 10A NCAC 14C.2702(c)(1), respectively, PET/CT Scanners are being held to an operational standard of 72 hours per week per 10A NCAC 14C.3702(b)(3)(B). Perhaps this requirement is based upon the lengthy total exam time of approximately 2 to 2.5 hours for PET. For example at TPH, the uptake time of the <sup>18</sup>F-DG is generally 90 to 120 minutes, followed by a scan that takes approximately 30 minutes. But, unlike CT and MRI that are used for innumerable indications, PET is used for a small subset of the general patient population that includes primarily oncology patients, and some cardiac and Alzheimer's patients. Furthermore, unlike CT and MRI which may be staffed to operate 24 hours a day to meet urgent and emergent needs, the daily PET schedule is limited to the availability of the cyclotron-produced <sup>18</sup>F-DG from regional vendors. At Presbyterian Hospital, we can scan a maximum of 14 patients per day and we have gained all the exam efficiency that is feasible. We must also take into account for certain PET studies the following complicating factors, some of which we can anticipate and some we cannot: late patients, diabetics, very ill patients (and the potential for radioactive body fluids), certain diseases requiring whole body PET scans, occasional sedation, and patients requiring interpreters.

One option to increase the productivity of the single PET/CT scanner at Presbyterian Hospital is to install a cyclotron to increase available hours of production. However, it is not a feasible alternative for Presbyterian Hospital to seek to add a cyclotron on site, as that equipment is regulated by both state CON and the federal United States Pharmacy 797 regulations (USP 797). USP 797 became effective in North Carolina and six other states in January 2007 and imposes a strict regulatory framework on the operation of cyclotron "hot labs" producing radiopharmaceuticals in NC. Thus, it is more cost effective for the large tertiary community hospital cancer and PET centers to purchase the radiopharmaceuticals from established third party vendors. In this type of arrangement, centers like the Presbyterian Hospital are limited to the times of day and days of the week when these vendors can produce and deliver the radiopharmaceuticals that are required. On the other hand, it is reasonable for the Academic Medical Centers (AMCs) to have the cyclotron on site to support the early research studies. Many of these cyclotrons were installed prior to the establishment of third party regional distribution centers.

In addition, the growth in the utilization of PET diagnostic studies for the Presbyterian Hospital Cancer Center oncology patient load has not permitted us to fully implement other more complex and time-intensive PET studies. For example, radiation treatment planning simulation studies can take as much as three times the normal scanner time of 30 minutes. Radiation Therapy treatment planning exams are time intensive and would be more available if TPH had more PET scanner capacity. Newer applications for cardiology patients have not been implemented because of the current time constraints. We anticipate that both of these applications may increase our PET volume, when we have adequate scanner time available. Since the availability of TPH's one PET/CT scanner is limited to just 14 patients per day as described above, we look forward to the opportunity to seek the state's approval for a second PET/CT scanner in 2008.

We have projected, conservatively, that the TPH PET annual PET scanner volumes will range from 2,600 to 2,900 by the end of CY 2009. Thus, if we are to plan in a way that allows our PET diagnostics to remain readily available to a growing variety of referring physicians and their patients, we must apply in the 2008 year to seek the state's approval for a second PET/CT scanner, which can be implemented in 2009. Otherwise, we think it is quite likely that the TPH PET scanner will reach the practical limits of its capacity and access to this valuable diagnostic service will be compromised. See Exhibit F.

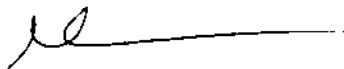


# Presbyterian HOSPITAL

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Thank you for the opportunity to present this letter in support of an amendment to proposed 2008 State Medical Facilities Plan to show the a need for one additional PET scanner in Health Service Area (HSA) III, which includes Mecklenburg County. If I may provide additional information, please contact me at (336)-384-4056.

Sincerely,



Robert Quarles, M.D., Medical Director, Nuclear Medicine and PET  
Mecklenburg Radiology Associates  
and  
Department of Radiology  
The Presbyterian Hospital

*File: PETTPHPetition08SMFPQuarlesRadiologistLetter.07.25.07.doc*

Presbyterian Hospital - PET Procedures

Inpatient & Outpatient - Combined Discharges Dated 01/01/2004 - 05/31/2007

Department 3927 - PET

EXHIBIT F

Oct 04	Nov 04	Dec 04	Jan 05	Feb 05	Mar 05	Apr 05	May 05	Jun 05	Jul 05	Aug 05	Sep 05	Oct 05	Nov 05	Dec 05
<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>	<u>Units</u>
67	100	74	109	114	110	132	163	164	176	178	157	125	166	172
1544 FFY 2005 Oct 04 thru Sep 05														
Avg PET Scans/Month---->												140.4		

File: PETProceduresTPHNov04-May07.xls

Exhibit F

Jan 06	Feb 06	Mar 06	Apr 06	May 06	Jun 06	Jul 06	Aug 06	Sep 06	Oct 06	Nov 06	Dec 06	Jan 07	Feb 07	Mar 07	Apr 07	May 07	Jun 07	Jul 07	Aug 07	Sep 07	Oct 07	Nov 07	Dec 07
Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units
160	161	209	165	174	151	140	203	162	171	172	173	174	175	176	177	178	179	180	181	182	183	184	
1988																							
FFY 06																							
Total																							
Oct 05 thru																							
Sep 06																							
165.7																							
Avg PET Scans/Month-->																							
2128																							
CY 2006																							
Total																							
Jan to Dec																							
2006																							
177.3																							
2325																							
FFY07																							
Appropriated																							
Oct 06 thru																							
Sep 07																							
199.8																							

# PRESBYTERIAN PET SCANS CALENDAR YEAR ( 2004 - 2009 )

(assumes future PET volume growth of 2% per Quarter)

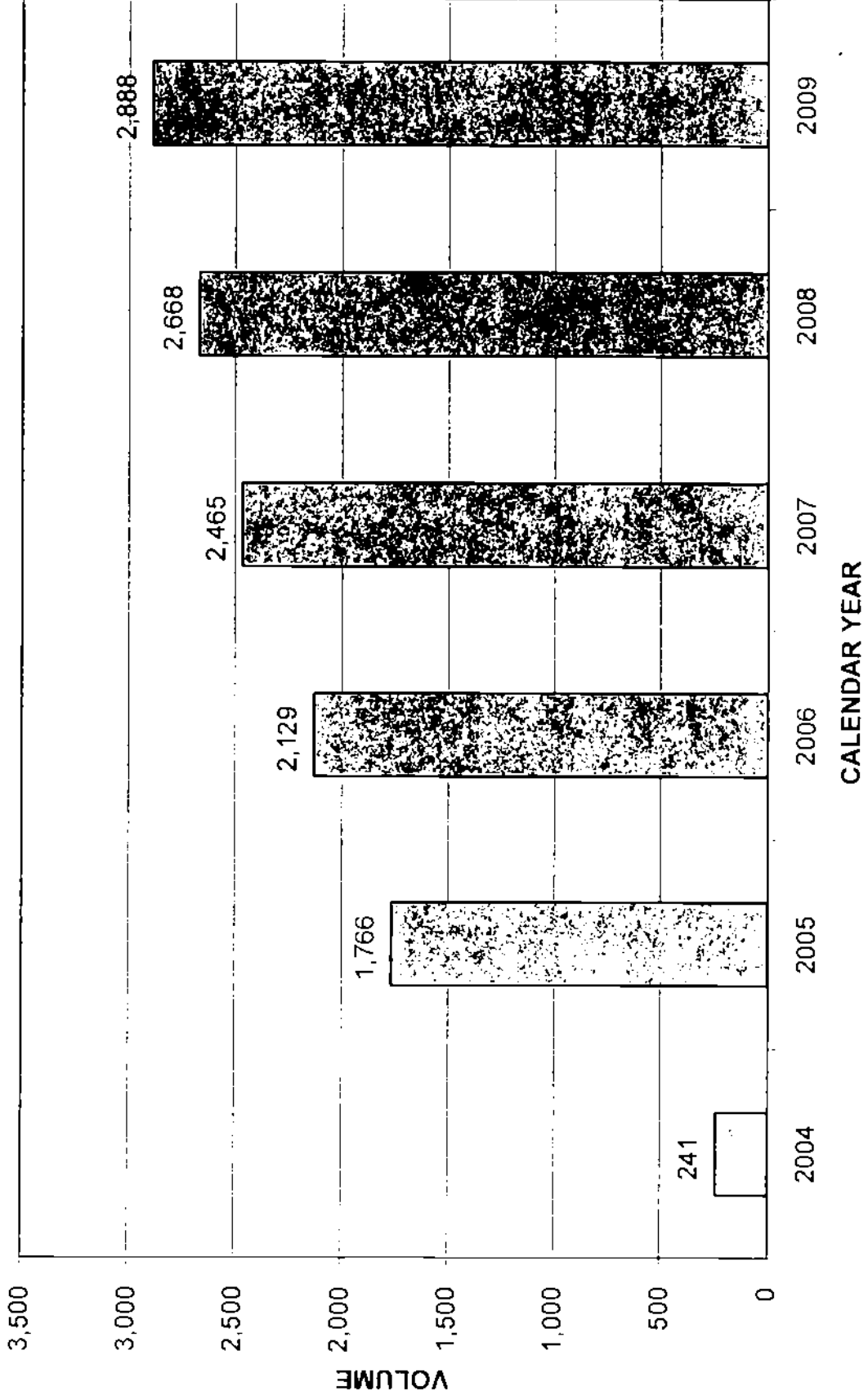


EXHIBIT G

Source: NOPR website

Cancers and indications that are reimbursable by Medicare are NOT eligible for entry in the NOPR. Cancers and indications that are specifically excluded for Medicare reimbursement are also not eligible for entry in the NOPR.

**IMPORTANT NOTE:** The scientific evidence concerning the clinical utility of FDG-PET is generally less robust for cancers and indications that are currently covered by Medicare only in the NOPR than for cancers and indications that are currently covered without clinical data submission to the NOPR. For this reason, Medicare has conditioned coverage of FDG-PET under the NOPR on the collection of clinical data. These data will be used to help determine the clinical utility of FDG-PET for conditionally covered cancers and indications. The billing physician remains responsible for documenting medical necessity, which is required for the coding and billing of both covered and NOPR-eligible PET studies. Eligibility for the NOPR does not constitute a clinical management recommendation for the use of PET for the conditionally covered cancers and indications, by either the Medicare program or NOPR investigators. Referring and interpreting physicians are thus advised to refer to the published literature to better understand the potential limitations of FDG-PET for NOPR-eligible uses.

CANCERS AND INDICATIONS ELIGIBLE FOR ENTRY IN THE NOPR

- ✓ = Eligible for Entry in NOPR
- C = Not Eligible for Entry in NOPR - nationally covered indication.
- NC = Not Eligible for Entry in NOPR - nationally non-covered indication.
- NA = Not Applicable

Indications	Diagnosis	Initial Staging	Treatment Monitoring	Restaging/Suspected Recurrence
Lip, Oral Cavity, and Pharynx (140-149)	C	C	✓	C
Esophagus (150)	C	C	✓	C
Stomach (151)	✓	✓	✓	✓
Small Intestine (152)	✓	✓	✓	✓
Colon (153) and Rectum (154)	C	C	✓	C
Anus (154)	✓	✓	✓	✓ <sup>1</sup>
Liver and intrahepatic bile ducts (155)	✓	✓	✓	✓

Gallbladder & extrahepatic bile ducts (156)	✓	✓	✓	✓	✓
Pancreas (157)	✓	✓	✓	✓	✓
Retropertoneum and peritoneum (158)	✓	✓	✓	✓	✓
Nasal cavity, ear, and sinuses (160)	C	C	C	✓	C
Larynx (161)	C	C	C	✓	C
Lung, non-small cell (162)	C	C	C	✓	C
Lung, small cell (162)	✓	✓	✓	✓	✓
Pleura (163)	✓	✓	✓	✓	✓
Thymus, heart, mediastinum (164)	✓	✓	✓	✓	✓
Bone/cartilage (170)	✓	✓	✓	✓	✓
Connective/other soft tissue (171)	✓	✓	✓	✓	✓
Melanoma of skin (172)	C	C <sup>2</sup>	C <sup>2</sup>	✓	C
Female breast (174)	NC <sup>3</sup>	C <sup>2</sup>	C <sup>2</sup>	C	C
Male breast (175)	NC <sup>3</sup>	C <sup>2</sup>	C <sup>2</sup>	C	C
Kaposi's sarcoma (176)	✓	✓	✓	✓	✓
Uterus, unspecified (179)	✓	✓	✓	✓	✓
Cervix (180)	✓	✓	C <sup>4</sup>	✓	✓
Uterus, body (182)	✓	✓	✓	✓	✓
Ovary and uterine adnexa (183)	✓	✓	✓	✓	✓
Prostate (185)	✓	✓	✓	✓	✓
Testis (186)	✓	✓	✓	✓	✓

Penis and other male genitalia (187)	✓	✓	✓	✓
Bladder (188)	✓	✓	✓	✓
Kidney and other urinary tract (189)	✓	✓	✓	✓
Eye (190)	✓	✓	✓	✓
Primary Brain (191)	✓	✓	✓	✓
Thyroid (193)	✓	✓	✓	C <sup>5</sup>
Lymphoma (200-202)	C	C	✓	C
Myeloma (203)	✓	✓	✓	✓
Leukemia (204-208)	✓	✓	✓	✓
Solitary Pulmonary Nodule	C	NA	NA	NA
Other or not listed	✓	✓	✓	✓

#### NOTES:

1. Some Medicare carriers include anal cancer in their coverage of "colorectal cancer"; for PET facilities served by those carriers, PET for anal cancer diagnosis, initial staging, or restaging/suspected recurrence would be a covered indication.
2. Does not cover initial staging for axillary lymph nodes for breast cancer patients and regional lymph nodes for melanoma patients
3. PET is non-covered for "Diagnosis" of breast cancer to evaluate a suspicious breast mass. However, a patient with suspected breast cancer is eligible for entry in NOPR for the indications (1) "Diagnosis: Unknown Primary Site" in a patient with axillary nodal metastasis but no evident primary breast cancer by conventional evaluation and (2) "Diagnosis: Paraneoplastic Syndrome".
4. Patient must have prior CT or MRI negative for extrapelvic metastatic disease to qualify as a covered indication. Patients who do not qualify for covered indication (e.g., because CT or MRI not done or because either showed extrapelvic metastatic disease) can be entered on NOPR.
5. To qualify as a covered indication thyroid cancer must be of follicular cell origin and been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin > 10ng/ml and negative I-131 whole body scan. Patients who do not qualify for covered indication (e.g., because tumor of other than follicular cell origin or thyroglobulin not elevated) can be entered on NOPR.

**GENERAL NOTE:**

*PET imaging of the brain with CPT code 78608 for diagnosis, initial staging, treatment monitoring, or restaging/suspected recurrence of any type of cancer is covered only under NPR.*

---

1818 Market Street, Suite 1600, Philadelphia, PA 19103 | 215.717.0859 | [petregistry.phila.acf.org](http://petregistry.phila.acf.org)



## Navigation

# NATIONAL ONCOLOGY PET REGISTRY


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## What is the NOPR?

### NOPR Background

The National Oncologic PET Registry (NOPR) was developed in response to the Centers for Medicare and Medicaid Services proposal to expand coverage for positron emission tomography with F-18 fluorodeoxyglucose (PET) to include cancers and indications not presently eligible for Medicare reimbursement. Medicare reimbursement for these cancers can now be obtained if the patient's referring physician and the provider submit data to a clinical registry to assess the impact of PET on cancer patient management. The NOPR is implementing this registry for CMS. The NOPR is sponsored by the Academy of Molecular Imaging and managed by the American College of Radiology through the American College of Radiology Imaging Network.

The NOPR received input from, and is endorsed by the ACR, the American Society for Clinical Oncology, and the Society for Nuclear Medicine.

### NOPR Status Update

The NOPR began accepting facility registrations in late November 2005 and patient registration began on May 8, 2006.

### How to Register as a Participating Site

Any PET facility that is approved to bill CMS for either technical or global charges can apply to participate in the NOPR. Sites are not required to have ACR or ICANL accreditation to participate. Interested facilities will register via the Facility Registration tool on the NOPR Web site, [www.CancerPETRegistry.org](http://www.CancerPETRegistry.org). The facility will complete the Facility Pre-Registration and Registration Forms online through the PET Facility Registration link. After completing the Registration process the facility must send an executed ACR HIPAA Business Associates Agreement (BAA) to NOPR Headquarters at 1818 Market Street, Philadelphia, PA 19103. The ACR HIPAA BAA is available on the NOPR Web site under Sample Forms. NOPR will assign a facility ID number and send an invoice for the facility registration fee (\$50) and the escrow account (amount determined by the facility).

### How to Register as a Participating Site

Any PET facility that is approved to bill CMS for either technical or global charges can apply to participate in the NOPR. Sites are not required to have ACR or ICANL accreditation to participate. Interested facilities will register via the Facility Registration tool on the NOPR Web site, [www.CancerPETRegistry.org](http://www.CancerPETRegistry.org). The facility will complete the Facility Pre-Registration and Registration Forms online through the PET Facility Registration link. After completing the Registration process the facility must send an executed ACR HIPAA Business Associates Agreement (BAA) to NOPR Headquarters at 1818 Market Street, Philadelphia, PA 19103. The ACR HIPAA BAA is available on the NOPR Web site under Sample Forms. NOPR will assign a facility ID number and send an invoice for the facility registration fee (\$50) and the escrow account (amount determined by the facility).

### Patient Eligibility

Medicare beneficiaries who are referred for PET for essentially all oncologic indications that are not currently reimbursable under Medicare are eligible to participate in the NOPR. The indications table lists the cancers and indications that will be accepted in the Registry.

### PET Facility Responsibilities

The PET facility is responsible for collecting and entering patient data into the Registry database through a web application at [www.CancerPETRegistry.org](http://www.CancerPETRegistry.org). Below is a brief summary of the data collection procedure.

- When a patient eligible for entry into the NOPR presents at the PET facility, the facility contacts the referring physician and obtains confirmation that the referring physician will submit the pre- and post-PET data requirements.
- The facility registers the patient on the NOPR via a Web form, at which time a Registry case number is assigned.
- The NOPR will e-mail confirmation to the PET facility and at the same time e-mail a request for the pre-PET form to the PET facility for delivery to the referring physician.
- The referring physician must complete and return the Pre-PLT form to the PET facility and the PET facility must enter the Pre-PLT Form into the NOPR database by midnight of the day of the PET scan.
- At some time before the PET study, or when the patient arrives for the PET scan, the PET facility will provide the patient with the ACR IRB-approved standard NOPR Patient Information Sheet that is posted on the NOPR Web site. The patient will be able to contact the NOPR directly for more information, if necessary. The patient will indicate his or her consent verbally to staff at the PET facility, either on the day of the PET study or within two working days after the PET study is completed. Written consent is not required. The PET facility will note in the database and on the PET Report Form, if the patient gave or withheld consent for use of his or her data in future NOPR research.
- After the PET scan is performed, the PET facility sends the PET report to the referring physician, enters the study completion date into a Web form, and submits the report text electronically to the NOPR database. Note that the PET scan must be completed and the PET Scan Completion Form must be entered into the database within 14 days of case registration or the case will be marked as ineligible.
- After the PET Scan Report Form is entered, the database will send the PET facility a patient-specific Post-PLT form for delivery to the referring physician. This form will also include an ACR IRB-approved Referring Physician Information Sheet. The physician will indicate on the Post-PET Form whether consent for use of the response data in future NOPR research has been given or withheld. All data will be sent to CMS, but the dataset used by NOPR investigators for research will contain only the data of patients and physicians when both have consented to have the data included. This form must be completed, returned to the PET facility, and entered into the NOPR database within 30 days of the PET scan.

### Referring Physician's Responsibilities

The patient's referring physician must agree to complete pre- and post-PET data collection forms consisting of approximately 5 questions regarding the patient's planned management.

- The Pre-PET Form must be completed by the referring physician and returned to the PET facility prior to the patient's PET scan. A blank Pre-PLT Form can be downloaded from the NOPR Web site and sent to the PET facility at the time of patient referral. If the form is not submitted with the referral a patient-specific form will be e-mailed to the PET facility for delivery to the referring physician. The Pre-PLT Form can be returned to the PET facility via FAX, mail, or hand delivery.
- After the PET is performed a patient-specific Post-PLT Form will be e-mailed to the PET facility for delivery to the referring physician for completion within 30 days. This form will also include an ACR IRB-approved Referring Physician Information Sheet. The physician will indicate on the Post-PET Form whether consent for use of the response data in future NOPR research has been given or withheld. All data will be sent to CMS, but the dataset used by NOPR investigators for research will contain only the data of patients and physicians when both have consented to have the data included. This form can also be returned to the PET facility via FAX, mail, or hand delivery.

The case is eligible for CMS reimbursement only if the Pre-PLT Form is completed and returned to the PET facility prior to the PET scan and the Post-PET Form is completed and returned within 30 days of the PET scan.

### How to Obtain Medicare Reimbursement

The NOPR database will notify the PET facility when all case data have been entered. The PET facility can then bill CMS for the study. The PET facility can check on the case status of their patients at any time via the reporting tools available on the NOPR Web site.

### Sponsored by:

- Academy of Molecular Imaging

### Endorsed by:

- American College of Radiology
- American Society of Clinical Oncology
- Society for Nuclear Medicine

**Managed by:**

- American College of Radiology
- American College of Radiology Imaging Network

**Advisor:**

- Centers for Medicare & Medicaid Services

**NOPR Working Group****■ Chair:**

- *Bruce Hillner, M.D.,*  
Virginia Commonwealth Univ.,  
(804) 828-5129  
hillner@vcu.edu

**■ Co-Chair:**

- *Barry Siegel, M.D.,*  
Washington University,  
(314) 362-2809  
siegel@wustl.edu
- *R. Edward Coleman, M.D.,*  
Duke University,  
(919) 684-7244  
colema011@mc.duke.edu
- *Anthony Shields, M.D.,*  
Wayne State University,  
(313) 576-8735  
shields@karmanos.org

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Vol. 16 • Issue 11 • Page 77  
PET Fancy

For treatment planning and evaluation of tumor response, radiation therapy departments are turning to PET and PET/CT.

By Sasa Mutic, MS

Volumetric patient imaging has become a cornerstone of modern radiation therapy practice, with its uses ranging from treatment planning to tumor detection and staging, and from daily patient positioning to evaluating treatment efficacy, outcomes and complications. These roles help define the ultimate goals of imaging in RT: to anatomically delineate and biologically characterize a tumor, select an appropriate therapy and predict tumor response as early as possible.

To accomplish these goals, RT must use both anatomical and biological imaging. Anatomical imaging delineates normal organs and tumors to the extent that they're anatomically visible on an image. Computed tomography (CT) and magnetic resonance imaging (MRI) are the main sources of anatomical imaging in RT. Biological imaging, on the other hand, doesn't need to indicate gross, anatomically visible changes; rather, it must capture information regarding a tumor's underlying physiology, metabolism, function and molecular makeup. No single imaging modality can accomplish all these goals, and RT patient management can involve CT, positron emission tomography (PET), MRI, single photon emission computed tomography (SPECT), ultrasound and planar radiography. Rather than compete, these imaging modalities are used in a complementary manner, and optimal patient treatment may require studies from several of these techniques.

### PET's rise in RT

Biological imaging in RT has grown rapidly in recent years, fueled by reports that imaging functional and biological tumor properties could improve disease detection, staging, treatment modality selection (intramodality and intermodality), target volume definitions, treatment planning, and outcome estimation and patient follow-up. PET, SPECT and MRI provide biological imaging information for RT treatment planning. In recent years, fluorine-18 fluorodeoxyglucose-based PET has become RT's main source of biological imaging information, and PET's increased usage in RT far outpaces MRI, SPECT and ultrasound. While the greatest advantage of FDG-based PET thus far has been improved staging, several reports also have shown that PET information can alter RT target volumes in approximately 30 percent of patients. Additionally, a concept of biological target volumes has been proposed. BTVs are portions of tumor volumes that have been identified with biological imaging as having increased importance due to properties that make those portions particularly difficult to eliminate. During RT planning, BTVs might receive increased dose and special considerations.

### The PET/CT effect

Beside clinical advantages, one main reason for PET's predominance in RT biological imaging has been the development of PET/CT scanners. A common problem with multimodality imaging for RT treatment planning is registration of images that are acquired in different scanners. The PET/CT scanner virtually eliminates this problem, as patients remain in the same position for the PET and CT portions of the scan. Patient movement and breathing motion still exist during image acquisition, and PET/CT registrations aren't perfect. However, these registrations are much more accurate and easier to implement than image registration from stand-alone scanners. Combined PET/CT scanners make biological imaging for RT treatment planning possible in routine clinical practice.

Many RT departments now house RT-dedicated PET/CT scanners or scanners that are shared between RT and nuclear medicine departments. Recognizing RT's demand for imaging studies, major imaging equipment manufacturers have made commercially available scanners designed for RT or possessing features designed for RT. This represents a paradigm shift from the 1980s and 1990s, when scanners were manufactured specifically



for diagnostic imaging, and any use for RT imaging required design modifications, often by the user. This change in the manufacturer's view of RT imaging is evident in the development of large-bore CT scanners—a segment of CT technology designed specifically for RT. This customization of imaging equipment also carried over to the design of PET/CT scanners, which are being equipped with tools common to CT simulators (flat tabletops, external lasers, respiratory gating, specialized virtual simulation software, etc.). These features allow PET/CT scanners to be installed in lieu of CT simulators, giving rise to the concept of the PET/CT simulator.

### PET on the move

Obviously, PET imaging for diagnosis and staging will remain with nuclear medicine facilities. However, PET scans for treatment planning and evaluation of tumor response during treatment could move to RT departments. Sound farfetched? Consider the fact that, not long ago, CT scanners were located mainly in diagnostic radiology, where most RT CT imaging was performed.

Clearly, PET's full potential in RT isn't yet fully understood. As additional studies are conducted and imaging equipment is improved further, the scope of PET imaging's influence on RT will become clearer. Current experience, however, suggests that an important segment of our patient population will require PET imaging for adequate management.

*Sasa Mutic, MS, is an associate professor of radiation oncology and chief of clinical physics service in the department of radiation oncology at Siteman Cancer Center, Mallinckrodt Institute of Radiology, Washington University School of Medicine, St. Louis.*

PET SIMULATORS

- Select One -

**MEASURABLY  
SUPERIOR  
OUTCOMES**

... adoption of direct order entry by community physicians

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**Technology and Equipment  
Committee Meeting**

**August 29, 2007**

**Positron Emission Tomography  
(PET) Scanner  
Material**

**Comments Related To**

**PET Petition: The Presbyterian Hospital**

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**Proposed 2008 State Medical Facilities Plan  
Public Hearing – August 1, 2007**

**Public Hearing Comments on Behalf of The Presbyterian Hospital  
Wallace C. Hollowell, III**

- Good afternoon. My name is Chuck Hollowell. I am an attorney with the law firm Nelson Mullins Riley & Scarborough, LLP. I am speaking today on behalf of The Presbyterian Hospital.
- Presbyterian submitted a petition for an adjustment to the PET scanner need determination in the Proposed 2008 State Medical Facilities Plan ("SMFP") at the July 25, 2007 public hearing in Charlotte.
- Today's remarks are made in support of this petition by Presbyterian.
- The need methodology for additional PET scanners in the Proposed 2008 SMFP provides that a need for an additional PET scanner is recognized when an existing fixed PET scanner is utilized at or above 80% of capacity, which has been set at 2,600 procedures per year. This means that a need is triggered when a fixed PET scanner is utilized at least 2,080 procedures per year.
- The time period used to make this calculation is the 12 month period reflected in the 2007 Hospital Licensure Applications - the 12 months ending September 30, 2006.
- Based on this 12 month period, Presbyterian's utilization rate for its PET scanner was 1,988 procedures, or 76.46% of capacity.
- This was only 92 procedures - or 3.5% - short of triggering a need for an additional PET scanner in HSA III.
- Presbyterian's PET utilization continues to grow rapidly.
- As shown in the materials submitted to the SHCC with Presbyterian's petition, for the 12 months ending November 30, 2006 - just *two months* beyond the data used in the Proposed 2008 SMFP - Presbyterian's PET scanner was used for 2,095 procedures, or 81% of capacity.
- For the 12 months ending December 31, 2006 - just *three months* beyond the data used in the Proposed 2008 SMFP - Presbyterian's PET scanner was utilized for 2,128 procedures, or 102% of capacity.
- Thus, if the standard need methodology is applied to data that is more current by only two or three months, then Presbyterian's utilization of its PET scanner clearly establishes a need for an additional PET scanner in HSA III.

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Planning Section

- Presbyterian's PET utilization is not only strong, but shows every indication that it will continue to increase.
- As set forth in detail in the materials submitted with Presbyterian's petition:
  - Presbyterian's average number of PET scans per month has increased each year since Presbyterian began providing PET services in October 2004;
  - Table 9K in the Proposed 2008 SMFP shows that Presbyterian ranks *third* out of 22 facilities in the State with PET scanners in terms of PET scanner utilization;
  - The Proposed 2008 SMFP recognizes that "the clinical use of PET scanning is increasing rapidly, and the new applications involve the diagnosis of cancer;"
  - It appears likely that other PET codes will be added for reimbursement, such as those for cancer treatment monitoring and re-staging of cancer recurrence; and
  - Table 9G in the Proposed 2008 SMFP shows that Presbyterian ranks *in the top ten* out of 64 facilities in the State providing radiation oncology service in the number of procedures performed.
- Thus, Presbyterian currently has one of the highest rates of utilization of its existing PET scanner of any scanner in the State, and this utilization is only expected to increase given the Presbyterian's robust cancer treatment program and the increasing number of cancer-related PET applications.
- Need determinations in the SMFP are not simply mathematical exercises. This is why the Proposed SMFP is published for public comment and why the SHCC considers petitions for adjustments to particular need determinations.
- Once the standard methodology has been applied to a snapshot of data from a particular time period, providers are allow to submit petitions to adjust the need determination based on other information that was not captured in the standard methodology and the data snapshot from a particular time period.
- Presbyterian's utilization numbers set forth in the Proposed 2008 SMFP show that it barely missed generating a need for an additional PET scanner in HSA III. These utilization numbers were based on a 12 month period that ended September 30, 2006.
- By looking at utilization data that is only two to three months more current, Presbyterian's utilization of its existing PET scanner easily generates a need for an additional PET scanner in this HSA.
- There are strong indications that Presbyterian's utilization of its PET scanner will only continue to increase.
- There is no reason why the SHCC should not consider this more current utilization data from Presbyterian. In fact, this petition process is explicitly designed so that this type of updated information from a particular hospital can be taken into account.
- As a result, Presbyterian respectfully requests that the SHCC consider the updated data regarding Presbyterian's utilization of its PET scanner and adjust the need determination in the Proposed 2008 SMFP to include the need for one additional PET scanner for HSA III.



**Survey: PET Scanner Weekly Hours of Operation**  
**July 2007**

	<b>Hours of Operation</b>	<b>Hours Per Week</b>
<b>Carolinas Medical Center Charlotte</b>	Monday - Friday 8:30 a.m. - 5:00 p.m.	42.5
<b>Duke University Medical Center</b>	Monday - Friday 6:30 a.m. - 6:30 p.m.	60
<b>Forsyth Medical Center</b>	Monday - Friday 6:30 a.m. - 11:00 p.m.	82.5
<b>Pitt County Memorial/ECU</b>	Monday - Friday 7:00 a.m. - 4:30 p.m.	42.5
<b>The Presbyterian Hospital</b>	Monday - Friday 6:30 a.m. - 5:30 p.m.	55
<b>WFU/North Carolina Baptist Hospital</b>	Monday - Friday 7:00 a.m. - 4:00 p.m.	40
<b>UNC</b>	Monday - Friday 7:00 a.m. - 4:00 p.m.	40
<b>High Point Regional Medical Center</b>	Monday - Friday 7:00 a.m. - 5:00 p.m.	50
<b>PET CON Regs at 10A NCAC 14C.3702(b)(3)(B)</b>	5x Day - Per Week 12 Hour - Per Day	75
<b>MRI CON Regs at 10A NCAC 14C.2702(c)(2)</b>	66 Hours Per Week	66
<b>Mobile MRI CON Regs at 10A NCAC 14C.2702(c)(3)</b>	40 Hours Per Week	40
<b>CT Scanner CON Regs at 10A NCAC 14C.2303(k)</b>	66 Hours Per Week	66
<b>Linear Accelerator CON Regs at 10A NCAC 14C.1902(b)(4)</b>	35 Hours Per Week	35
<b>Operating Room CON Regs at 10A NCAC 14C.2103(a) &amp; SMFP</b>	5 Days Per Week 9 Hours Per Day	45
<b>PET Data Sources: Dr Coleman's Letter (DUMC), PET Supervisors &amp; Techs, CMC web site</b> <b>File: PETScannerHoursOfOperation.07.31.2007.xls</b>		

**2008 Proposed SMFP Public Hearing  
July 25, 2007---1:30 PM, Charlotte NC**

**Presbyterian Hospital: Request for Adjusted Need Determination to Add  
One New PET Scanner for HSA III in the Proposed 2008 SMFP**

**Hearing Remarks of Robert Quarles, M.D.  
Nuclear Medicine and PET Medical Director, Department of Radiology  
Presbyterian Hospital, Charlotte, NC  
Board Certified Radiologist, Mecklenburg Radiology Associates**

- I have been involved with PET technology since 1987-1988 and it is the single most important tool to be developed in nuclear medicine in this generation
- PET is essentially a scan performed using a radioactively labeled sugar as the imaging agent. Because cancer cells consume a large amount of sugar, the PET can detect and then pinpoint the tumor more effectively than any other imaging modality.
- The Presbyterian Hospital PET scanner has undergone a rapid ramp up since it became operational in October 2004, experiencing growth of 18 to 20 percent annual growth in PET scans when comparing the first 6 months to the first six months of 2007. Please refer to the exhibits enclosed that highlight the extent of growth in PET scans at Presbyterian Hospital.
- In projecting the need for a second PET scanner at Presbyterian, 2 percent growth factor per quarter was utilized or approximately 10 percent on an annual basis. This is very conservative given the actual annual growth rate of 18 - 20 percent since PET services began.
- If Presbyterian Hospital must wait beyond the 2008 CON Plan year to seek the state's approval for an additional PET scanner, we project that the single PET scanner at TPH will be performing 2,600 to 2,900 PET scans per year. This is well beyond the practical limits of the capacity of a single PET scanner.
- Based on actual PET volumes and anticipated growth, Presbyterian will need to file a CON application in mid 2008 in order to go through the CON process and ensure that a second PET scanner comes on line to meet increased the increased demand and avoid an unacceptable bottleneck in access to diagnostic PET studies for our patients and their referring physicians. Therefore, we are seeking in the 2008 SMFP a need determination for one new PET scanner in HSA III now, so that patient access and quality of care can be maintained.
- The Presbyterian Cancer Center is one of the ten busiest cancer centers in the state with Duke, Forsyth Medical Center, and Moses Cone Health System making up the top three. Over 95 percent of the scans done at Presbyterian Hospital are cancer related.

**2008 Proposed SMFP Public Hearing  
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**Presbyterian Hospital: Request for Adjusted Need Determination to Add  
One New PET Scanner for HSA III in the Proposed 2008 SMFP**

- Presbyterian Hospital will implement a third linear accelerator in Ballantyne in 2008 which will significantly increase radiation therapy treatments. This will add to the need and demand for PET services related to cancer services.
- The National Oncologic PET Registry (NOPR) was established in 2005 by the Centers for Medicare and Medicaid Services (CMS) to expand coverage for PET scans with F-18 fluorodeoxyglucose (FDG-18). Currently CMS covers nine cancers and indications for Medicare reimbursement. However, as a result of the NOPR, it is expected that the Medicare coverage will be expanded. Once this occurs more indications for PET diagnostic studies will be eligible for reimbursement. This will also serve to continue the upward trend in the demand for PET diagnostic studies at TPH.
- PET is rapidly becoming the standard of care in cancer services at busy cancer centers like TPH. As the use of PET diagnostic studies in cancer care continues to grow, other diagnostic uses of PET are also expanding. For example, PET is also being recognized as an effective tool in cardiac, Alzheimer's and other areas. Because our scanner is operating close to capacity with a full load of PET diagnostic studies for cancer patients, we lack the necessary flexibility to fully expand PET diagnostic for additional specialties and patients that would benefit. A second PET scanner at TPH would create the necessary additional capacity to allow that growth to occur and be readily accommodated.

*File: PETPresbyPetitionRemarksDrQuarlesPublicHr08SMFPCharlotte07-25-2007.doc*

**2008 Proposed SMFP Public Hearing  
July 25, 2007---1:30 PM, Charlotte NC**

**Presbyterian Hospital: Request for Adjusted Need Determination to Add  
One New PET Scanner for HSA III in the Proposed 2008 SMFP**

**Hearing Remarks of Wendy Burkart, BSRT, MHA  
Director of Radiology Services  
Presbyterian Hospital, Charlotte, NC**

- I want to emphasize what Drs. McGinnis and Quarles and Cindi have already commented on and that is the fact that given the current and future PET demands at Presbyterian Hospital, a second PET scanner is a necessity.
- Dr. Coleman of Duke University has been quoted estimating that the demand for PET services will increase at a rate of 15 percent per year. With double digit growth in this modality, Presbyterian Hospital will be unable to accommodate the growth, not will we be positioned to accommodate new applications emerging in cardiology and neurology.
- The standard of care is transitioning to the use of PET/CT for radiation treatment planning. This process requires 90 minutes of scan/table tie as compare to 30 minutes for PET/CT scan time. This translated to an increased burden on the existing PET scanner.
- As Dr. Quarles stated we are only 4 percent shy of the 2,080 adjusted scan threshold. Our conservative quarterly volume projections indicate Presbyterian's PET growth at 2 percent. This corresponds to the 8 - 10 percent annual growth compared to our actual annual growth of approximately 20 percent since beginning operation in October 2004. Based on these assumptions, PET volumes will range from 2,600 to 2,900 by the end of calendar year 2009 -- well beyond the current threshold of 2,080.
- In addition, Presbyterian Hospital is currently above the 12,500 radiation treatment threshold at 16,659. Accordingly Presbyterian Hospital will implement a third linear accelerator in 2008. Cancer services continue to expand within the Presbyterian system and PET scans are an essential element in the diagnosis, staging, and treatment of a variety of cancers.
- These factors coupled with Presbyterian Hospital's strong growth necessitate additional PET technology in HSA III for 2008. If a need is determined in 2008, the PET scanner will not become operational until 2009 when our volume projections indicate we will be performing well over the state threshold.

*File: PETPresbyPetitionRemarksBurkartPublicHR08SMFPCCharlotte 07-25-07.doc*

**2008 Proposed SMFP Public Hearing  
July 25, 2007---1:30 PM, Charlotte NC**

**Presbyterian Hospital: Request for Adjusted Need Determination to Add  
One New PET Scanner for HSA III in the Proposed 2008 SMFP**

**Hearing Remarks of Cindi Gilbert, BHS, CNMT, PET, RT(N)  
Supervisor of PET Services  
Presbyterian Hospital**

- FDG-18 is the radioactive dose injected into the patient in order to find "hot spots" typical of cancer in the human body.
- This radioactivity decays very quickly and cannot be stored for later use. Currently our doses come to us from 1 ½ hours away
- The radioactivity is ordered per patient by the patient's weight, type of PET scan, and time of injection. So if a patient is late or not prepared for the scan the dose is wasted..
- Our doses come as unit doses, one dose per patient drawn up in a syringe, and not a bulk multi-dose vial. We are not equipped with robotic arms to draw up these doses from a multi-dose vial plus the radiation burden to the technologists would reach upper ALARA limits.
- The commercial suppliers of the FDG-18 do not make the doses past late morning so to get additional doses for later in the day scanning is extremely difficult and not cost effective. This would cause major financial and staffing changes for the commercial suppliers as well. These vendors may not be willing to provide service for one hospital. We are currently under contract with a vendor and are at its mercy.
- FDG suppliers cannot be expected to operate past normal operating hours in order to be cost effective therefore it is not feasible to arbitrarily expand the PET operating hours. Additionally patients already compromised by cancer or undergoing treatment cannot be expected to undergo scans at late or very early hours outside of the norm.
- Even if we were to somehow able to access doses for the afternoon and have them delivered in the morning, the hot lab would have unacceptably high radioactive levels for the staff.
- Unlike the academic centers that have a cyclotron in their institutions, we cannot make FDG-18 as needed. Plus we absorb the cost of each dose not utilized. This makes us different than academic institutions.
- We could purchase a cyclotron for \$2.3 million, fit it with the USP-797 clean room regulations, and bring in a radiopharmacist to make the doses and an engineer to run it. With this idea, losing a dose or two per day would not be an issue as it is for the clinical institutions. However, a cyclotron is not cost-effective in clinical facilities like Presbyterian.

**2008 Proposed SMFP Public Hearing  
July 25, 2007---1:30 PM, Charlotte NC**

**Presbyterian Hospital: Request for Adjusted Need Determination to Add  
One New PET Scanner for HSA III in the Proposed 2008 SMFP**

(Cindi Gilbert Remarks continued)

- Our patients arrive; thirty minutes apart, they are injected with radioactivity, wait 90 minutes for FDG uptake, and are scanned approximately 30 minutes typically. The uptake time protocol is the same as Duke University's.
- With that information in mind, knowing that the limiting factors of FDG availability, other work flow barriers include patients arriving to the department late (the dose has decayed to a point it is unusable and very ill patients being injected in a timely fashion. Diabetic patients whose blood glucose level is elevated must have their scans canceled as well as patients arriving that are non-prepped. Again, we absorb the cost of these doses.
- We try very hard to obtain patient information prior to the patient's arrival but this is not always successful.
- When a radiation therapy patient arrives, I block the schedule so the next two patients coming in are an hour after the radiation therapy patient. This patient's scan takes up almost three times the amount of time that a traditional oncology patient takes. These issues create a work flow barrier to our institution.
- Presbyterian Hospital's PET is staffed from 6:30 AM to 6 PM Monday through Friday. Patients are scheduled from 7 AM to 5 PM. These operating hours are consistent and reasonable compared with other NC PET scanners facilities. Only mobile PET vendors operate on weekends.
- The American College of Radiology (ACR) will request CMS to consider reimbursing for other cancers immediately following ASNC in November. A decision should come from CMS within 6 months.
- Also CMS is currently reviewing an indication for PET reimbursement. This is for fever of unknown origin (FOU). A decision should be made within the next few months. As the Medicare reimbursement expands and other payers follow, PET service demand and volumes will only increase putting more strain on the one scanner at Presbyterian Hospital. A second scanner is necessary to meet our immediate need as well as the projected cancer and other specialty indications expected in the near future.

*File: PETPresbyPetitionRemarksCindiGilbertPublicHRO8SMFPCharlotte 07 25 2007(2).doc*

**2008 Proposed SMFP Public Hearing  
July 25, 2007---1:30 PM, Charlotte NC**

**Presbyterian Hospital: Request for Adjusted Need Determination to Add  
One New PET Scanner for HSA III in the Proposed 2008 SMFP**

**Hearing Remarks of L. Scott McGinnis, M.D.,  
Radiation Therapy Medical Director, Presbyterian Cancer Center  
Presbyterian Hospital, Charlotte, NC**

- PET is crucial to oncology services as the most accurate technology available to pinpoint and target tumors. Since many tumors are undetectable on routine imaging equipment, PET has the unique ability to scan and detect cancer at a molecular level. Early detection and thus earlier treatment results in better outcomes.
- Beyond the diagnosis, PET can be used in radiation therapy and in the ongoing assessment of therapy and in determining the need or result of surgery. PET usage lowers the need for additional surgeries, chemotherapy or radiation therapy with its more precise imaging.
- PET technology fused with CT scanning capabilities is an important aspect in cancer services. Integrated PET technology has been one of the most significant advances in diagnostic imaging in the past decades.
- PET/CT technology improves outcomes as the tumor is targeted as a "hot spot" allowing noncancerous tissue to remain undamaged during the radiation therapy. This leads to better quality treatment with increased patient benefit.
- PET is the leading tool in use with Tumor Boards and in conjunction with Presbyterian's Multidisciplinary Clinics that currently involve breast, GI, melanoma and prostate cancers.
- The Presbyterian Hospital PET scanner is at capacity and is experiencing an increase of 10 – 15 percent over the past five years. At this rate of growth, without consideration of new clinical applications or increased reimbursement coverage, Presbyterian Hospital's PET scanner will be operating at more than the state threshold by 2009.
- To promote access and to remain efficient in providing quality diagnostic and treatment options, a second PET scanner is necessary at Presbyterian Hospital. The increased use of PET in radiation therapy planning consumes more time than a diagnostic PET scan – almost triple the time. In order to accommodate the use of PET diagnostics for superior radiation therapy treatment planning while continuing to meet the ongoing demand for diagnostic PET scans, another PET scanner would prove more cost-effective while meeting the needs of our cancer patients.

**2008 Proposed SMFP Public Hearing  
July 25, 2007---1:30 PM, Charlotte NC**

**Presbyterian Hospital: Request for Adjusted Need Determination to Add  
One New PET Scanner for HSA III in the Proposed 2008 SMFP**

- The Presbyterian Cancer Center is one of ten busiest cancer centers in North Carolina. This fact, in addition to a third linear accelerator to begin operating in 2008 will only increase the demand for PET diagnostic services at Presbyterian.

*File: PETPresbyPetitionremarksDrMcGinnisPublicHr08SMFPCharlotte 07 25 2007.doc*



**Technology and Equipment  
Committee Meeting**

**August 29, 2007**

**Positron Emission Tomography  
(PET) Scanner  
Material**

**Comments Related To**

**PET Need Determination in Proposed 2008 SMFP:  
Forsyth Medical Center**

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COMMENT TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL  
REGARDING THE NEED DETERMINATION FOR POSITRON EMISSION  
TOMOGRAPHY SCANNERS IN THE 2008 STATE MEDICAL FACILITIES PLAN

Forsyth Medical Center ("Forsyth") submits this comment to the North Carolina State Health Coordinating Council ("SHCC"), in support of the need determination contained in the Proposed 2008 State Medical Facilities Plan ("SMFP") at Table 9M, page 122, for a fixed dedicated positron emission tomography ("PET") scanner in Health Service Area ("HSA") II.

Forsyth is a non-profit corporation operating a full service hospital in Winston-Salem with 751 licensed acute care beds. Forsyth offers a comprehensive cancer program with four linear accelerators currently in operation. As shown in the Proposed 2008 SMFP, Forsyth provided 28,435 radiation oncology procedures in the most recent annual period for which information is available.

Forsyth may be contacted about this Comment directly or through its counsel, at the following addresses:

Novant Health, Inc.  
Forsyth Medical Center  
Gregory J. Beier, President  
3333 Silas Creek Parkway  
Winston-Salem, NC 27103  
Telephone: (336) 718-2015  
[gjbeier@novanthealth.org](mailto:gjbeier@novanthealth.org)

Nelson Mullins Riley & Scarborough LLP  
Noah H. Huffstetler, III  
Counsel for Novant Health and  
Forsyth Medical Center  
4140 Parklake Avenue, Suite 200  
Raleigh, NC 27612  
Telephone: (919) 877-3801  
[noah.huffstetler@nelsonmullins.com](mailto:noah.huffstetler@nelsonmullins.com)

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Medical Facilities  
PLANNING SECTION

On page 121, the Proposed 2008 SMFP provides in pertinent part:

One additional fixed dedicated PET scanner is needed for each existing fixed PET scanner that was utilized at or above 80% of capacity during the twelve month period reflected in the owner's or operator's 2007 Hospital Licensure Renewal Application on file with the N.C. Division of Facility Services. For the purposes of this determination, the annual capacity of a fixed dedicated PET scanner is  $(2,600 \times .80 = 2,080)$  procedures. . . .

Applying this methodology, Table 9M on page 122 of the Proposed 2008 SMFP shows a need for one additional fixed PET scanner in HSA II, in which Forsyth is located. For the period covered by its 2007 annual license renewal application, the twelve months ending September 30, 2006, the utilization rate for Forsyth's PET scanner was 2,417 procedures, or 92.96% of capacity. This utilization of Forsyth's equipment based on PET scans per scanner ranks first among the twenty-two facilities in North Carolina with fixed PET scanners.

Moreover, the data set forth in Exhibit A to this Petition shows that the utilization of Forsyth's PET scanner continues to grow rapidly. The growth in Forsyth's PET scanning services is likely not only to continue, but to accelerate. The discussion of PET utilization contained at pages 116-118 of the Proposed 2008 SMFP recognizes "the steady growth in the number of clinical studies for which the Centers for Medicare and Medicaid Services ("CMS") authorizes reimbursement for PET scanning," and concludes that "the clinical use of PET scanning is increasing rapidly, and the new applications involve the diagnosis of cancer." In addition, the CMS National Oncologic PET Registry (NOPR)<sup>1</sup> is tracking data to determine if other PET codes should be added for reimbursement beyond the current codes that focus on PET scans used for initial diagnosis and staging of cancer patients. It is likely that the data will show

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<sup>1</sup> Dr. Coleman, Vice Chair, Department of Radiology, Professor of Radiology, Director of Nuclear Medicine, Duke University Medical Center, is Co-Chair for NOPR.

that PET scans for cancer treatment monitoring and re-staging of cancer recurrence should also be added as reimbursable PET scan codes. See Exhibit E. As shown on Table 9G at pages 108-09 of the Proposed 2008 SMFP, Forsyth's radiation oncology service ranks second among the sixty-four facilities providing that service in North Carolina in the number of procedures performed.<sup>2</sup> Given the robust and growing cancer treatment programs offered by Forsyth, and the rapidly increasing number of types of cancer for which PET scanning is useful, it is clear that Forsyth's PET utilization is likely to grow even more quickly in the coming years. This is further substantiated by the letter of Dr. Basile, Medical Director for Inpatient Radiology at Forsyth Medical Center, which is attached as Exhibit B to this Petition.

Despite the clear evidence that an additional PET scanner is needed in HSA II as indicated in the draft 2008 SMFP on page 119, Forsyth is concerned that there may be an attempt to deprive it of the opportunity to apply for a certificate of need to acquire the needed equipment. At the May 16, 2007 meeting of the SHCC's Technology and Equipment Committee, it was suggested that the threshold to trigger a need determination for an additional PET scanner should be raised to 2,500 procedures or more per year<sup>3</sup>. Moreover, Forsyth has received notice that a "PET Scanner Discussion Group Meeting" has been scheduled for August 15, 2007. For all of the reasons set forth below, no attempt should be made to change the statewide methodology for making PET scanner need determinations in the 2008 SMFP.

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<sup>2</sup> As measured by ESTV-weighted radiation therapy treatment procedures: (1) Duke @ 36,634; (2) FMC @ 28,435; (3) Moses Cone Health System @ 28,362; (4) Cape Fear Valley Medical Center @ 27,631; (5) First Health Moore Regional @ 23,764; (6) UNC Hospitals @ 22, 224; (7) Mission Hospitals @ 20,776; (8) NCBH @ 20,251; (9) Catawba Valley Medical Center @ 20,766; (10) The Presbyterian Hospital @ 16,659. See Exhibit D.

<sup>3</sup> Based on a discussion at the May 16, 2007 meeting of the SHCC's Medical Equipment and Technology Committee. The Chair of the Committee discussed a letter from Dr. Coleman at Duke University Medical Center (DUMC) that stated "our experience suggests that the capacity of a fixed dedicated PET CT scanner is 15 procedures a day...If 15 per day were capacity, a fixed dedicated PET CT scanner could provide 3,750 procedures per year (15 X 250). Given the length of time required to bring an additional machine on line, I would make the threshold a volume of 10 procedures per day or 2,500 per year." See Exhibit C for a copy of Dr. Coleman's letter. An additional calculation shows that the 2,500 PET procedures year threshold is 67% of 3,750 PET procedures year assumed annual capacity.

First, the Agency's performance standards codified at 10A N.C.A.C. 14C.3703 require an applicant proposing to acquire a PET scanner to demonstrate that "its existing dedicated PET scanners . . . performed an average of at least 2,080 PET procedures per PET scanner in the last year."<sup>4</sup> If the proposed change in the 2008 SMFP were adopted, the 2,080 procedure threshold would be accordingly adjusted to 2,500 procedures, and should be applicable to any future application for new or replacement equipment. Because the cost of PET equipment typically exceeds \$2,000,000, a CON is normally required to replace an existing scanner. For example, during 2007 Duke University Medical Center submitted a CON application to replace a PET scanner with a new PET/CT scanner and the associated project capital cost was \$3.7 Million (Project I.D. # J-7794-07); the project was approved under the 2,080 utilization standard. Therefore, if the threshold for a PET scanner need determination is raised to 2,500 procedures<sup>5</sup> per year, many existing providers of PET scanning services will be unable to replace their existing equipment when it reaches the end of its useful life, if they are not able to establish that the annual utilization of their PET scanner will exceed the new higher volume threshold of 2,500 PET procedures per year. Furthermore, the PET need method does not include any weighting factors for PET procedures (as the MRI and CT scan regulations and need method do), so this would make it even more difficult for all applicants seeking to replace and update original PET and PET/CT scanners to demonstrate the need in a CON application. Moreover, any attempt by

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<sup>4</sup> The 2,080 PET procedures/year threshold is 80% of the annual capacity of a PET scanner 2,600 PET procedures/year. ( $\sim 2,600 \times .80 = 2,080$ ). This PET scanner capacity definition and utilization threshold to trigger need for a new PET scanner is found in the 2007 SMFP at page 115 and in the draft 2008 SMFP at page 121.

<sup>5</sup> Based on a discussion at the May 16, 2007 meeting of the SHCC's Medical Equipment and Technology Committee. The Chair of the Committee discussed a letter from Dr. Coleman at Duke University Medical Center (DUMC) that stated "our experience suggests that the capacity of a fixed dedicated PET/CT scanner is 15 procedures a day...If 15 per day were capacity, a fixed dedicated PET/CT scanner could provide 3,750 procedures per year ( $15 \times 250$ ). Given the length of time required to bring an additional machine on line, I would make the threshold a volume of 10 procedures per day or 2,500 per year." See Exhibit C for a copy of Dr. Coleman's letter. An additional calculation shows that the 2,500 PET procedures/year threshold is 67% of 3,750 PET procedures/year assumed annual capacity.

the Certificate of Need Section to exempt a certificate of need application to replace existing equipment from the new standard would arbitrary and capricious, and therefore subject to legal challenge.

Second, the argument for raising the assumed capacity is premised in part on the current requirement in 10A N.C.A.C. 14C.3702(b)(3)(B) that a PET scanner be operated for "a minimum of twelve hours per day, six days a week." However, the seventy-two hours of weekly operation required for a PET scanner is inconsistent with the sixty-six hours per week required for similar technologies like a MRI scanner, under 10A N.C.A.C. 14C.2702(c)(1), and a CT scanner, under 10A N.C.A.C. 14C.2302(k). A PET scanner should not be expected to operate more weekly hours than those other diagnostic modalities. This point is reinforced by the views expressed in the letter attached as Exhibit B, in which Dr. Basile maintains that it is unreasonable to expect a PET scanner to be operated as many hours per week as a CT or MRI unit<sup>6</sup>.

Finally, it is procedurally inappropriate to implement a fundamental change in a methodology for the 2008 SMFP having statewide implications in a specially convened August 15<sup>th</sup>, 2007 meeting of a "Discussion Group." As explained on page 7 of the 2007 SMFP:

Persons who wish to recommend changes that may have a statewide effect are asked to contact the Medical Facilities Planning staff as early in the year as possible, and to submit petitions no later than **March 7**. Changes with the potential for a statewide effect are the addition, deletion, and revision of policies and revision of the projection methodologies. These types of changes will need to be considered in the first four months of the calendar year as the "Proposed SMFP" ... is being developed.

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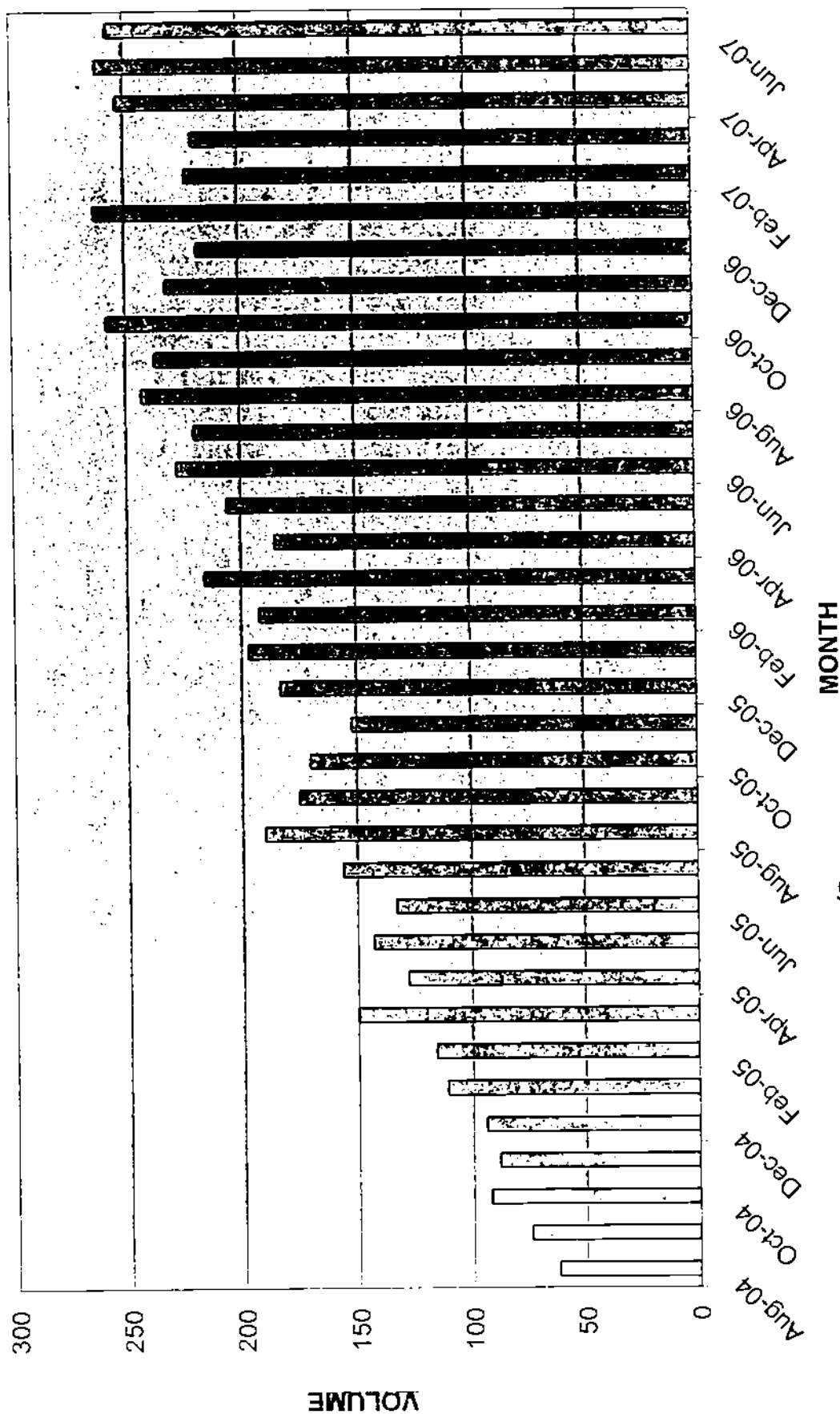
<sup>6</sup> Dr. Coleman's May 2007 letter to the SHCC's Medical Equipment and Technology Committee suggests that, at that time, the DUMC PET/CT scanner was operated 12 hours per day on weekdays (Monday – Friday) or 60 hours per week.

Any such change could first be considered by the full SHCC at its September meeting, after the "Public Review and Comment Period" which includes six public hearings conducted throughout the State on the Proposed 2008 SMFP, and which concludes on August 3, 2007. To change a statewide methodology after any opportunity for public comment on the 2008 SMFP has ended would clearly violate the established procedures for the annual update of the SMFP. Thus, the earliest such a change could properly be implemented is in the 2009 SMFP.

Given the foregoing considerations, Forsyth respectfully submits that the 2008 SMFP should include a determination that an additional fixed dedicated PET scanner is needed HSA III, and that any proposal to change the statewide methodology for making such need determinations should be considered in accordance with the established State Health Planning Process for possible inclusion in the 2009 SMFP.

*File: PETCommentFMCToSHCC08ProposedSMFP.07.20.07.doc*

# FMC PET SCANS BY MONTH

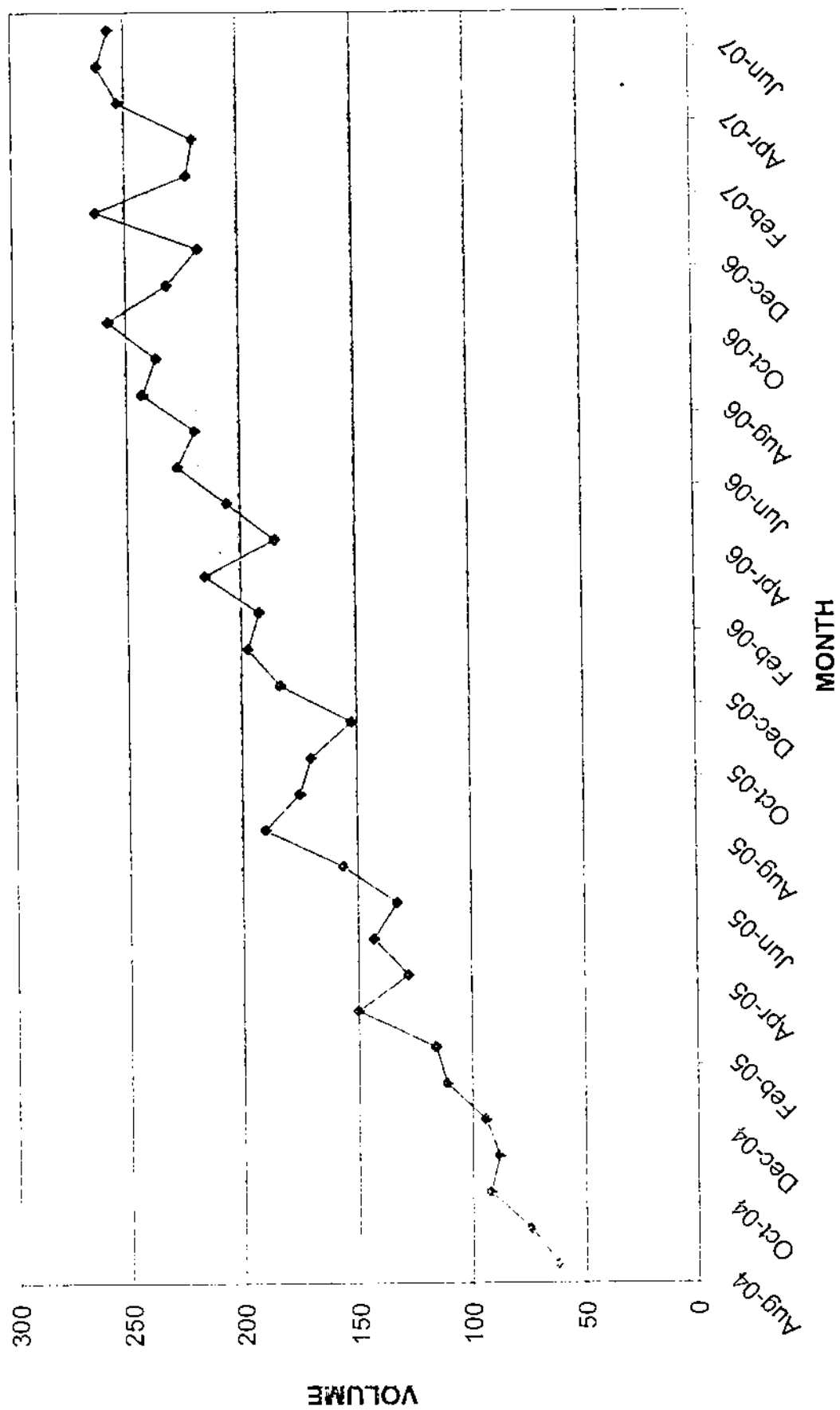


FFY04 PET Scans = 130  
 FFY05 PET Scans = 1579  
 FFY06 PET Scans = 2,417  
 FFY07 PET Estimated = 2,914 (based on 9 Months of Data)

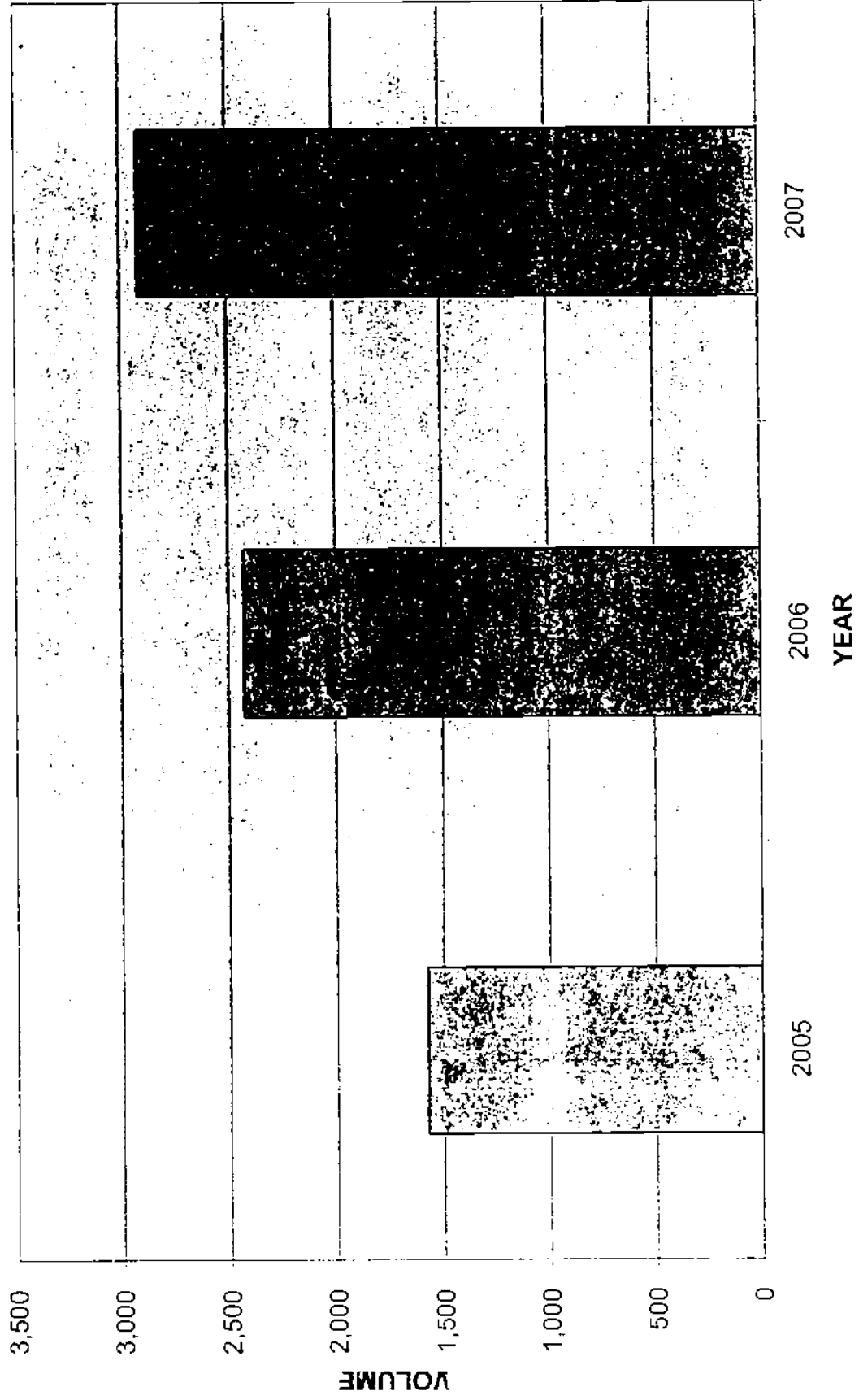


# EXHIBIT A

FMC PET SCANS BY MONTH



# FMC PET SCANS FEDERAL FISCAL YEAR





July 19, 2007

Chris Ullrich, M.D., Chair  
 Medical Equipment and Technology Committee  
 State Health Coordinating Council  
 701 Barbour Drive  
 Raleigh, NC 27603

Subject: Comment to the State Health Coordinating Council Regarding the Need Determination for One New PET Scanner for HSA II in the Proposed 2008 State Medical Facilities Plan

Dear Dr. Ullrich:

I support of the Need Determination for a fixed dedicated positron emission tomography (PET) scanner in Health Service Area (HSA) II contained in the Proposed 2008 State Medical Facilities Plan (SMFP). An additional scanner is needed as PET services will clearly continue to grow.

Forsyth Medical Center (FMC) began offering PET services in August 2004 and since then we have completed over 6000 exams. As shown below, the average number of exams per month has increased steadily and is currently almost 250 per month. Over 90% of these exams have been completed on oncology patients. FMC's Derrick L. Davis/Forsyth Regional Cancer Center is the second busiest cancer center in the state second only to Duke, when measured by the number of ESTV radiation therapy treatments offered during FFY 2006 as reported in the proposed 2008 SMFP. FMC's oncology program has experienced sustained growth over the past several years and this growth is expected to continue. Thus a second PET scanner will become necessary not only to keep up with the growing demand from cancer physicians and their patients, but also to allow the expansion of FMC's PET studies to additional specialists and their patients.

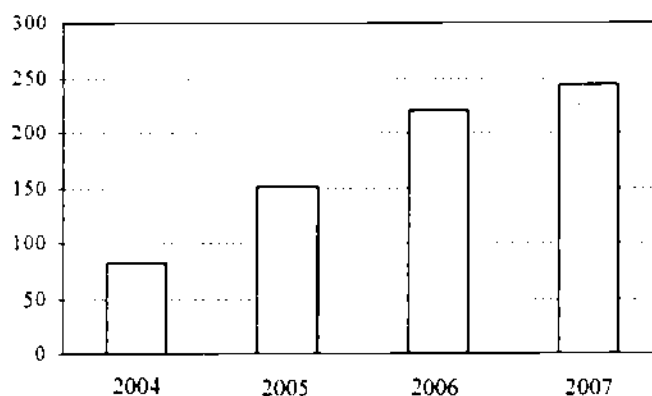


Figure 1. Average number of PET exams per month for each year that PET has been available at Forsyth Medical Center, Winston-Salem, NC.

<sup>1</sup> Based on ESTV-weighted radiation therapy procedures report in the Proposed 2008 SMFP: (1) Duke at 36,634; (2) FMC at 28,435; (3) Moses Cone Health System at 28,362; (4) Cape Fear Valley Medical Center at 27,631; (5) First Health Moore Regional at 23,764; (6) UNC Hospitals at 22,224; (7) Mission Hospitals at 20,776; (8) NCBH at 20,251; (9) Catawba Valley Medical Center at 20,766; (10) The Presbyterian Hospital at 16,659.

With regard to PET growth, the National Oncologic PET Registry (NOPR) was established in 2005 in response to a proposal by the Centers for Medicare and Medicaid Services (CMS) to expand coverage for PET with F-18 fluorodeoxyglucose (<sup>18</sup>FDG) to include cancers and indications not presently eligible for Medicare reimbursement. Prior to May 2006 when the NOPR began registering patients to capture data on additional oncologic indications for the use of PET scans, CMS paid for PET scans for only nine types of cancer. The attached table from the NOPR website (<http://www.cancerpetregistry.org>) shows the types of cancers and indications for which PET scans are already covered by Medicare (designated with a "C"). It also shows the additional cancers and indications for which Medicare reimbursement is available through the NOPR (designated with a "v") if the patient's referring physician and the provider submit data to the clinical registry to assess the impact of PET diagnostic information on cancer patient management. Sponsored by the Academy of Molecular Imaging and managed by the American College of Radiology through the American College of Radiology Imaging Network, the NOPR is implementing this registry for CMS. Considering the impact of the NOPR, PET will surely continue to grow as the CMS begins to cover for more cancers the diagnosis, initial staging, treatment monitoring during therapy (chemotherapy, radiation therapy, or combined modality therapy) and re-staging after completion of therapy and detection of suspected recurrence.

A PET/CT scanner should not be expected to operate more weekly hours than other diagnostic modalities such as computed tomography (CT) or magnetic resonance imaging (MRI). Unlike CT or MRI that must operate 66 hours per week as per 10A NCAC 14C.2302(k) or 10A NCAC 14C.2702(c)(1), respectively, PET/CT scanners are being held to an operational standard of 72 hours per week per 10A NCAC 14C.3702(b)(3)(B). Perhaps this requirement is based upon the lengthy total exam time of approximately 2 to 2.5 hours for PET. For example, the uptake time of the <sup>18</sup>FDG is generally 60 to 90 minutes, followed by a scan that takes approximately 25 to 30 minutes. But, unlike CT and MRI that are used for innumerable indications, PET is used for a small subset of the general patient population that includes primarily oncology patients. Furthermore, unlike CT and MRI which may be staffed to operate 24 hours a day to meet urgent and emergent needs, the daily PET schedule is limited to the availability of the cyclotron-produced <sup>18</sup>FDG from regional vendors – at FMC, we are only able to offer access to PET services only 12 hours per day.

Oncology is only one specialty that utilizes PET. For example, cardiology patients may benefit from <sup>18</sup>FDG exams to assess myocardial viability and neurology patients may benefit from exams to diagnose Alzheimer's as Medicare does reimburse PET scans for these indications. But because FMC is committed to providing the best patient care in a timely manner, we have not yet fully introduced our PET services to the cardiologists or neurologists nor have we begun to implement therapy treatment planning with the radiation oncologists. Since the availability of FMC's one PET/CT scanner is limited to just 12 hours per day as described above, we look forward to the opportunity to seek the state's approval for a second PET/CT scanner in 2008. This will better enable us to provide excellent service to a wider variety of referring physicians whose patients would benefit from PET diagnostic studies.

Thank you for the opportunity to provide comments in support of the Health Service Area (HSA) II PET Scanner Need Determination in the Proposed 2008 State Medical Facilities Plan. If I may provide additional information, please contact me at (336) 718-5844.

Sincerely,



Vito Basile, M.D., Medical Director  
Department of Radiology  
Forsyth Medical Center

National Oncologic PET Registry (NOPR)  
**Cancers and Indications Eligible for Entry into NOPR**  
 (Information available at <http://www.cancerpetregistry.org/indications.htm>)

Indications	Diagnosis	Staging	Restaging	Monitoring
Anus	✓	✓	✓	✓
Bladder	✓	✓	✓	✓
Bone/cartilage	✓	✓	✓	✓
Brain, Primary	✓	✓	✓	✓
Breast, female	NC	C1	C	C
Breast, male	✓	✓	✓	✓
Cervix	✓	C2	✓	✓
Colon and Rectum	C	C	C	✓
Connective/other tissue	✓	✓	✓	✓
Esophagus	C	C	C	✓
Eye	✓	✓	✓	✓
Gallbladder and extrahepatic bile ducts	✓	✓	✓	✓
Kaposi's sarcoma	✓	✓	✓	✓
Kidney and other urinary tract	✓	✓	✓	✓
Larynx	C	C	C	✓
Leukemia	✓	✓	✓	✓
Lip, Oral Cavity, and Pharynx	C	C	C	✓
Liver and intrahepatic bile ducts	✓	✓	✓	✓
Lung, non-small cell	C	C	C	✓
Lung, small cell	✓	✓	✓	✓
Lymphoma	C	C	C	✓
Melanoma of skin	C	C1	C	✓
Myeloma	✓	✓	✓	✓
Nasal cavity, ear, and sinuses	C	C	C	✓
Ovary and uterine adnexa	✓	✓	✓	✓
Pancreas	✓	✓	✓	✓
Penis and other male genitalia	✓	✓	✓	✓
Pluera	✓	✓	✓	✓
Prostate	✓	✓	✓	✓
Retropentoneum and pentoneum	✓	✓	✓	✓
Single Pulmonary Nodule	C	NA	NA	NA
Small Intestine	✓	✓	✓	✓
Stomach	✓	✓	✓	✓
Testis	✓	✓	✓	✓
Thymus, heart, mediastinum	✓	✓	✓	✓
Thyroid	✓	✓	C3	✓
Uterus, body	✓	✓	✓	✓
Uterus, unspecified	✓	✓	✓	✓
Other or not listed	✓	✓	✓	✓

✓ Eligible for entry in NOPR

C Not eligible for entry in NOPR (because already nationally covered indication)

NC Not eligible for entry in NOPR (because nationally non-covered indication)

NA Not applicable

- Does not cover initial staging for axillary lymph nodes for breast cancer patients and regional lymph nodes for melanoma patients
- Patient must have prior CT or MRI negative for extrapelvic metastatic disease to qualify as a covered indication. Patients who do not qualify for covered indication (e.g., because CT or MRI not done or because either showed extrapelvic metastatic disease) can be entered on NOPR.
- To qualify as a covered indication thyroid cancer must be of follicular cell origin and been previously treated by thyroidectomy and radiiodine ablation and have a serum thyroglobulin > 10 ng/ml and negative I-131 whole body scan. Patients who do not qualify for covered indication (because tumor other than follicular cell origin or thyroglobulin not elevated) can be entered on NOPR.



DUKE UNIVERSITY MEDICAL CENTER

R. Edward Coleman, M.D.  
Professor and Vice Chairman  
Department of Radiology

DFS Health Planning  
RECEIVED

MAY 15 2007

Medical Facilities  
Planning Section

May 14, 2007

Mr. Tom Elkins, Planner  
Medical Facilities Planning Section  
Division of Facility Services  
N. C. Department of Health & Human Services  
701 Barbour Drive  
Raleigh, NC 27603

Re: PET/CT Capacity

Dear Tom:

Duncan forwarded me your question about the feasibility of increasing the capacity of fixed dedicated PET scanners in the need methodology incorporated in the State Medical Facilities Plan.

For several reasons your inquiry is perfectly timed:

1. The PET/CT scanners now being purchased are significantly faster than the PET-only scanners that they have replaced. In short, we now have enough experience with the PET/CT to revise the need methodology to assume its use.
2. The technology has stabilized. The PET/CT we will install later this year is no faster or more efficient than the PET/CT we installed 4 years ago, and I do not foresee any significant change in the years ahead.

Our experience suggests that the capacity of a fixed dedicated PET/CT scanner is 15 procedures a day. During the year ended June 30, 2006 our PET/CT provided 3,327 procedures, for an average of 13.3 per day. With the demand continuing to increase, we have lengthened our schedule and our PET/CT now averages 15 procedures per day.

To maintain that volume, our staff arrives about 6:30 A.M. every weekday, the first patient is scheduled at 6:45 A.M., the last patient is scheduled at 5:00 P.M. but is usually scanned close to 6:00 P.M., and the service closes at 6:30 P.M.

Tom Eikins  
May 14, 2007  
Page 2

If 15 per day were capacity, a fixed dedicated PET/CT scanner could provide 3,750 procedures per year (15 x 250). Given the length of time required to bring an additional machine on line, I would make the threshold a volume of 10 procedures per day or 2,500 per year. Even though new indications will not expand the use of PET scanning in the next few years, the demand is likely to continue increasing about 15% per year, and we in North Carolina should be positioned to meet that demand.

I hope that these suggestions are helpful. If you have questions or need further information, please let me know.

Sincerely,



R. Edward Coleman, M.D.  
Vice Chair, Department of Radiology  
Professor of Radiology  
Director of Nuclear Medicine

cc: Duncan Yaggy

## Proposed 2008 SMFP

Table 9K: PET Scanner Utilization of Existing Fixed Dedicated Scanners

Center	Procedures				HSA	Inventory	Utilization Rate	Need Determination by Criteria - 80% of Present Capacity
	2002- 2003	2003- 2004	2004- 2005	2005- 2006			Year 2006 Procedures 2600 as Capacity	
Mission Hospitals (f)		644	875	1003	I	1	38.58%	
Catawba Valley/ Frye Reg. (i)			848	1258	I	1	48.38%	
N.C. Baptist Hospitals	1817	1797	1266	1477	II	1	56.81%	
Moses Cone Health System (o)			1352	1760	II	1	67.69%	
Forsyth Medical Center (p)		130	1579	2412	II	1	92.96%	1
High Point Regional (r)		179	356	574	II	1	22.08%	
Alamance Reg. Medical Ctr. (u)				374	II	1	14.38%	mobile procedures
Carolinas Med Center(a),(k)	2414	2908	3049	3635	III	2	69.90%	
Gaston Mem. / CIS Summit (m)		172	700	846	III	1	32.54%	
NorthEast Medical Center (n)		330	481	615	III	1	23.65%	
The Presbyterian Hospital (q)			1544	1988	III	1	76.46%	
Iredell Memorial Hospital (t)				NA	III	1	NA	
Duke Univ. Hospital (d)	3259	3135	3091	3596	IV	2	69.15%	
UNC Hospitals (b)	1230	1389	1144	1386	IV	2	26.65%	
Rex Hospital (e)	407	1116	1544	1913	IV	1	73.58%	
Wake PET Services, Wake Radiology Oncology, Wake Radiology, WakeMed (s)				NA	IV	1		
New Hanover Reg. Med. (g)			582	755	V	1	29.04%	
Cape Fear Valley Medical Ctr. (h)		629	1218	2069	V	1	79.58%	0
First Imaging of the Carolinas (i)		351	529	550	V	1	21.15%	
Pitt Co. Memorial (c)		418	393	832	VI	1	32.00%	
Craven Reg. Medical (l)			719	831	VI	1	31.96%	
Nash General Hospital (u)				336	VI	1	12.92%	mobile procedures
TOTAL	9,127	13,198	21,270	28,215		25		1

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NA Not Applicable for time period ending September 30, 2006.

- (a) Approved for additional scanner in November 2001.  
 (b) Approved for scanner in June 2000 and additional scanner under Policy AC-3 in November 2005.  
 (c) Approved for scanner in August 2001.  
 (d) Approved for additional scanner under Policy AC-3 in September 2002.  
 (e) Approved for scanner in September 2002.  
 (f) Approved for scanner in January 2003.  
 (g) Operational in October 2004.  
 (h) Approved for scanner in August 2003.  
 (i) Approved for scanner in August 2003.  
 (j) Approved for scanner in July 2003.  
 (k) Approved for replacement of 1 scanner in June 2003.
- (l) Approved for scanner in October 2003.  
 (m) Approved for scanner in December 2003.  
 (n) Approved for scanner in December 2003.  
 (o) Operational in October 2004.  
 (p) Approved for scanner in June 2004.  
 (q) Approved for scanner in June 2004.  
 (r) Approved for scanner in January 2005.  
 (s) Approved for scanner in November 2005.  
 (t) Approved for scanner in January 2007.  
 (u) Approved for scanner in April 2007.  
 (v) Approved for scanner in May 2007.



**Table 9G: Hospital and Free-Standing Linear Accelerators  
and Radiation Oncology Procedures (see note at bottom of table)**

Facility Name	Service Area #	County	LIN ACC	PROCEDURES (ESTVs)	
				2005-2006	Average per Unit
Harris Regional Hospital, Inc.-Mtn Trace	1	Jackson	1	4,503	4,503
NC Radiation Therapy - Franklin	1	Macon	1	2,277	2,277
Mission Hospitals (S) (b)	2	Buncombe	3	(20,766)	6,922
NC Radiation Therapy - Asheville	2	Buncombe	2	7,012	3,506
NC Radiation Therapy - Clyde	2	Haywood	1	4,359	4,359
NC Radiation Therapy - Marion	2	McDowell	1	2,534	2,534
Watauga Hospital	3	Watauga	1	4,491	4,491
Margaret Pardee Mem. Hospital	4	Henderson	1	6,591	6,591
NC Radiation Therapy - Brevard	4	Transylvania	1	1,709	1,709
NC Rad. Therapy - Hendersonville	4	Henderson	1	645	645
Catawba Valley Medical Center	5	Catawba	2	(18,008)	9,004
Frye Regional Medical Center	5	Catawba	1	NA	NA
Grace Hospital, Inc.	5	Burke	1	NR	NR
Valdese General	5	Burke	1	6,082	6,082
Caldwell Memorial Hospital, Inc.	5	Caldwell	1	1,056	1,056
Cleveland Regional	6	Cleveland	1	6,989	6,989
Gaston Memorial Hospital (h)	6	Gaston	3	11,761	3,920
NC Radiation Therapy - Forest City	6	Rutherford	1	4,656	4,656
2006 SMFP Need Determination	7		1		
Carolinas Medical Center (S)	7	Mecklenburg	3	14,128	4,709
CMC-Union Reg. Medical Center ( i )	7	Union	1	8,428	8,428
Matthews Radiation Oncology	7	Mecklenburg	1	10,803	10,803
Presbyterian Hospital	7	Mecklenburg	4	(16,659)	4,165
University Radiation Oncology	7	Mecklenburg	1	7,289	7,289
Iredell Memorial	8	Iredell	2	6,834	3,417
Lake Norman Radiation Oncology Ct	8	Iredell	1	4,641	5,525
Rowan Regional Medical Center	8	Rowan	1	5,519	5,519
NorthEast Medical Center	9	Cabarrus	2	13,009	6,505
Stanly Regional Medical Center	9	Stanly	1	4,427	4,427
Forsyth Memorial Hospital	10	Forsyth	4	(28,435)	7,109
Hugh Chatham Memorial Hospital (d)	10	Surry	1	3,911	3,911
N. C. Baptist Hospitals (S)	10	Forsyth	4	(20,251)	5,063
2006 SMFP Need Determination	11	Davidson	1		
High Point Regional Health System	12	Guilford	2	9,344	4,672
Morhead Memorial Hospital	12	Rockingham	1	5,972	5,972
Moses Cone Health System	12	Guilford	4	(28,362)	7,091
Randolph Cancer Center (m)	13	Randolph	1	NA	NA
UNC Hospitals (S)	14	Orange	4	(22,224)	5,556

**Table 9G: Hospital and Free-Standing Linear Accelerators  
and Radiation Oncology Procedures (see note at bottom of table)**

Facility Name	Service Area #	County	LIN ACC	PROCEDURES (ESTVs)	
				2005-2006	Average per Unit
Alamance Regional Medical Center (j)	15	Alamance	2	7,991	3,996
Duke University Hospital (S)	16	Durham	5	(36,634)	7,327
Durham Regional Hospital	16	Durham	1	6,128	6,128
Maria Parham Hospital (c)	16	Vance	1	4,833	4,833
FirstHealth Moore Regional	17	Moore	2	(23,764)	11,882
Scotland Memorial Hospital (1)	17	Scotland	1	4,122	4,122
Cape Fear Valley Medical Center (a)	18	Cumberland	4	(27,631)	6,908
Southeastern Regional Medical Center	18	Robeson	1	9,484	9,484
New Hanover Radiation Oncology	19	New Hanover	2	(15,156)	7,578
New Hanover Regional Med Ctr	19	New Hanover	1	7,599	7,599
South Atlantic Radiation Oncology, LLC (c)	19	Brunswick	1	NA	0
2007 SMFP Need Determination	20		1		
Cancer Ctrs of NC - Raleigh Hematology	20	Wake	1	8,924	8,924
Duke Raleigh Hospital	20	Wake	1	7,323	7,323
Rex Hospital	20	Wake	4	16,184	4,046
Wake Radiology Oncology Services	20	Wake	1	5,960	5,960
Triangle Radiation Oncology Services	21	Johnston	1	2,648	1,093
2006 SMFP Need Determination	21	Johnston	1		
Lenoir Memorial	22	Lenoir	1	6,147	6,147
Wayne Radiation Oncology Center	22	Wayne	1	6,952	6,952
Carteret General (g)	23	Carteret	1	4,015	4,015
Craven Regional Med Ctr	23	Craven	2	12,415	6,208
2006 SMFP Need Determination	24	Onslow	1		
Nash Day Hospital	25	Nash	2	7,905	3,953
Roanoke Valley Cancer Center	25	Halifax	1	3,208	3,208
Wilson Memorial Hospital	25	Wilson	1	4,413	4,413
Ahoskie Cancer Center	26	Hertford	1	3,173	3,173
Carolina Radiation Medicine, P.A. (f) (S)	26	Pitt	1	8,206	8,206
Pitt County Memorial Hospital (S)	26	Pitt	3	16,013	5,338
Albemarle Hospital	27	Pasquotank	1	4,403	4,403
Outer Banks Cancer Center	27	Dare	1	4,977	4,977
<b>TOTALS (64 Facilities)</b>			<b>112</b>	<b>579,883</b>	<b>5,178</b>

Note: The above inventory of linear accelerators is subject to change if it is determined that any of the listed equipment was not acquired in accordance with N.C. G. S. 131E-175, et seq, prior to August 26, 2005.

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EXHIBIT E

Source: NOPR website

Cancers and indications that are reimbursable by Medicare are NOT eligible for entry in the NOPR. Cancers and indications that are specifically excluded for Medicare reimbursement are also not eligible for entry in the NOPR.

**IMPORTANT NOTE:** The scientific evidence concerning the clinical utility of FDG-PET is generally less robust for cancers and indications that are currently covered by Medicare only in the NOPR than for cancers and indications that are currently covered without clinical data submission to the NOPR. For this reason, Medicare has conditioned coverage of FDG-PET under the NOPR on the collection of clinical data. These data will be used to help determine the clinical utility of FDG-PET for conditionally covered cancers and indications. The billing physician remains responsible for documenting medical necessity, which is required for the coding and billing of both covered and NOPR-eligible PET studies. Eligibility for the NOPR does not constitute a clinical management recommendation for the use of PET for the conditionally covered cancers and indications, by either the Medicare program or NOPR investigators. Referring and interpreting physicians are thus advised to refer to the published literature to better understand the potential limitations of FDG-PET for NOPR-eligible uses.

**CANCERS AND INDICATIONS ELIGIBLE FOR ENTRY IN THE NOPR**

- ✓ = Eligible for Entry in NOPR
- C = Not Eligible for Entry in NOPR - nationally covered indication.
- NC = Not Eligible for Entry in NOPR - nationally non-covered indication.
- NA = Not Applicable

Indications	Diagnosis	Initial Staging	Treatment Monitoring	Restaging/Suspected Recurrence
Lip, Oral Cavity, and Pharynx (140-149)	C	C	✓	C
Esophagus (150)	C	C	✓	C
Stomach (151)	✓	✓	✓	✓
Small Intestine (152)	✓	✓	✓	✓
Colon (153) and Rectum (154)	C	C	✓	C
Anus (154)	✓	✓	✓	✓
Liver and intrahepatic bile ducts (155)	✓	✓	✓	✓

Gallbladder & extrahepatic bile ducts (156)	✓	✓	✓	✓	✓
Pancreas (157)	✓	✓	✓	✓	✓
Retropertitoneum and peritoneum (158)	✓	✓	✓	✓	✓
Nasal cavity, ear, and sinuses (160)	C	C	✓	✓	C
Larynx (161)	C	C	✓	✓	C
Lung, non-small cell (162)	C	C	✓	✓	C
Lung, small cell (162)	✓	✓	✓	✓	✓
Pleura (163)	✓	✓	✓	✓	✓
Thymus, heart, mediastinum (164)	✓	✓	✓	✓	✓
Bone/cartilage (170)	✓	✓	✓	✓	✓
Connective/other soft tissue (171)	✓	✓	✓	✓	✓
Melanoma of skin (172)	C	C <sup>1</sup>	✓	✓	C
Female breast (174)	NC <sup>3</sup>	C <sup>1</sup>	C	C	C
Male breast (175)	NC <sup>3</sup>	C <sup>1</sup>	C	C	C
Kaposi's sarcoma (176)	✓	✓	✓	✓	✓
Uterus, unspecified (179)	✓	✓	✓	✓	✓
Cervix (180)	✓	C <sup>4</sup>	✓	✓	✓
Uterus, body (182)	✓	✓	✓	✓	✓
Ovary and uterine adnexa (183)	✓	✓	✓	✓	✓
Prostate (185)	✓	✓	✓	✓	✓
Testis (186)	✓	✓	✓	✓	✓

Penis and other male genitalia (187)	✓	✓	✓	✓
Bladder (188)	✓	✓	✓	✓
Kidney and other urinary tract (189)	✓	✓	✓	✓
Eye (190)	✓	✓	✓	✓
Primary Brain (191)	✓	✓	✓	✓
Thyroid (193)	✓	✓	✓	C <sup>b</sup>
Lymphoma (200-202)	C	C	✓	C
Myeloma (203)	✓	✓	✓	✓
Leukemia (204-208)	✓	✓	✓	✓
Solitary Pulmonary Nodule	C	NA	NA	NA
Other or not listed	✓	✓	✓	✓

#### NOTES:

1. Some Medicare carriers include anal cancer in their coverage of "colorectal cancer"; for PET facilities served by those carriers, PET for anal cancer diagnosis, initial staging, or restaging/suspected recurrence would be a covered indication.
2. Does not cover initial staging for axillary lymph nodes for breast cancer patients and regional lymph nodes for melanoma patients
3. PET is non-covered for "Diagnosis" of breast cancer to evaluate a suspicious breast mass. However, a patient with suspected breast cancer is eligible for entry in NOPR for the indications (1) "Diagnosis: Unknown Primary Site" in a patient with axillary nodal metastasis but no evident primary breast cancer by conventional evaluation and (2) "Diagnosis: Paraneoplastic Syndrome".
4. Patient must have prior CT or MRI negative for extrapelvic metastatic disease to qualify as a covered indication. Patients who do not qualify for covered indication (e.g., because CT or MRI not done or because either showed extrapelvic metastatic disease) can be entered on NOPR.
5. To qualify as a covered indication thyroid cancer must be of follicular cell origin and been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin > 10ng/ml and negative I-131 whole body scan. Patients who do not qualify for covered indication (e.g., because tumor of other than follicular cell origin or thyroglobulin not elevated) can be entered on NOPR.

#### GENERAL NOTE:

PET imaging of the brain with CPT code 78608 for diagnosis, initial staging, treatment monitoring, or restaging/suspected recurrence of any type of

Cancer is covered only under *NOPR*.

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1818 Market Street, Suite 1600, Philadelphia, PA 19103 | 215.717.0859 | [pet registry.phila.acr.org](http://petregistry.phila.acr.org)

## NOPR

## NATIONAL ONCOLOGIC PET REGISTRY


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## What is the NOPR

### NOPR Background

The National Oncologic PET Registry (NOPR) was developed in response to the Centers for Medicare & Medicaid Services proposal to expand coverage for positron emission tomography with F-18 fluoro-deoxyglucose (FDG) to include cancers and indications not presently eligible for Medicare reimbursement. Medicare beneficiaries can now be obtained if the patient's referring physician and the provider submit a request to the NOPR to assess the impact of PET on cancer patient management. The NOPR is implemented by CMS. The NOPR is sponsored by the Academy of Molecular Imaging and managed by the American College of Radiology Imaging Network.

The NOPR received input from, and is endorsed by the ACR, the American Society for Clinical Oncology, and the Society for Nuclear Medicine.

### NOPR Status Update

The NOPR began accepting facility registrations in late November 2005 and patient registrations in early 2006.

### How to Register as a Participating Site

Any PET facility that is approved to bill CMS for either technical or global charges can participate in the NOPR. Sites are not required to have ACR or ICANL accreditation to participate. Interested parties can register via the Facility Registration tool on the NOPR Web site, [www.CancerPETRegistry.org](http://www.CancerPETRegistry.org). The Facility Pre-Registration and Registration Forms online through the PET Facility Registration process the facility must send an executed ACR HIPAA Business Associates Agreement to the ACR Headquarters at 1818 Market Street, Philadelphia, PA 19103. The ACR HIPAA BAA is a site under Sample Forms. NOPR will assign a facility ID number and send an invoice for the registration fee (\$50) and the escrow account (amount determined by the facility).

### How to Register as a Participating Site

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### Patient Eligibility

Medicare beneficiaries who are referred for PET for essentially all oncologic indications reimbursable under Medicare are eligible to participate in the NOPR. The following are the indications that will be accepted in the Registry.

### PET Facility Responsibilities

The PET facility is responsible for collecting and entering patient data into the Registry application at [www.CancerPETRegistry.org](http://www.CancerPETRegistry.org). Below is a brief summary of the data collected:

- When a patient eligible for entry into the NOPR presents at the PET facility, the referring physician and obtains confirmation that the referring physician will submit data requirements.
- The facility registers the patient on the NOPR via a Web form, at which time a facility ID is assigned.
- The NOPR will e-mail confirmation to the PET facility and at the same time e-mail a form to the PET facility for delivery to the referring physician.

- The referring physician must complete and return the Pre-PET Form to the PET facility. The PET facility must enter the Pre-PET Form into the NOPR database by midnight of the day of registration.
- At some time before the PET study, or when the patient arrives for the PET scan, the PET facility will provide the patient with the ACR IRB-approved standard NOPR Patient Information Sheet. The patient will be able to contact the NOPR directly for more information. The patient will indicate his or her consent verbally to staff at the PET facility, before the PET study or within two working days after the PET study is completed. Written consent from the PET facility will note in the database and on the PET Report Form, if the patient has consented for use of his or her data in future NOPR research.
- After the PET scan is performed, the PET facility sends the PET report to the referring physician. The PET facility will enter the PET scan completion date into a Web form, and submits the report text electronically to the NOPR database. Note that the PET scan must be completed and the PET Scan Completion Form must be entered into the database within 14 days of case registration or the case will be marked as ineligible.
- After the PET Scan Report Form is entered, the database will send the PET facility a Post-PET Form for delivery to the referring physician. This form will also include an Attending Physician Information Sheet. The physician will indicate on the Post-PET Form whether the response data in future NOPR research has been given or withheld. All data submitted to the database will be used by NOPR investigators for research. The dataset used by NOPR investigators for research will contain only the data of physicians when both have consented to have the data included. This form must be completed, signed, and entered into the NOPR database within 30 days of the PET scan.

### Referring Physician's Responsibilities

The patient's referring physician must agree to complete pre- and post-PET data collection. The physician will answer approximately 5 questions regarding the patient's planned management.

- The Pre-PET Form must be completed by the referring physician and returned to the PET facility before the patient's PET scan. A blank Pre-PET Form can be downloaded from the NOPR Web site. The PET facility will provide the form at the time of patient referral. If the form is not submitted with the referral, the PET facility will e-mail the form to the PET facility for delivery to the referring physician. The form can be delivered to the PET facility via FAX, mail, or hand delivery.
- After the PET scan is performed, a patient-specific Post-PET Form will be e-mailed to the referring physician for completion within 30 days. This form will also include an Attending Physician Information Sheet. The physician will indicate on the Post-PET Form whether the response data in future NOPR research has been given or withheld. All data submitted to the database will be used by NOPR investigators for research. The dataset used by NOPR investigators for research will contain only the data of physicians when both have consented to have the data included. This form can be delivered to the PET facility via FAX, mail, or hand delivery.

The case is eligible for CMS reimbursement only if the Pre-PET Form is completed and returned to the PET facility prior to the PET scan and the Post-PET Form is completed and returned within 30 days of the PET scan.

### How to Obtain Medicare Reimbursement

The NOPR database will notify the PET facility when all case data have been entered. The PET facility will then bill CMS for the study. The PET facility can check on the case status of their patients at any time using the tools available on the NOPR Web site.

### Sponsored by:

- Academy of Molecular Imaging

### Endorsed by:

- American College of Radiology
- American Society of Clinical Oncology
- Society for Nuclear Medicine

### Managed by:

- American College of Radiology
- American College of Radiology Imaging Network

### Advisor:



- Centers for Medicare & Medicaid Services

#### **NOPR Working Group**

- **Chair:**

- *Bruce Hillner, M.D.,*  
Virginia Commonwealth Univ.,  
(804) 828-5129  
b.hillner@vcu.edu

- **Co-Chair:**

- *Barry Siegel, M.D.,*  
Washington University,  
(314) 362-2809  
bsiegel@wustl.edu
- *R. Edward Coleman, M.D.,*  
Duke University,  
(919) 684-7244  
rc@mc023.mc.duke.edu
- *Anthony Shields, M.D.,*  
Wayne State University,  
(313) 576-8735  
ashields@karmanos.org

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1818 Market Street, Suite 1600, Philadelphia, PA 19103

| 215.717.0659

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**Proposed 2008 State Medical Facilities Plan  
Public Hearing – August 1, 2007**

**Public Hearing Comments on Behalf of Forsyth Medical Center**  
Wallace C. Hollowell, III

Medical Facilities  
PLANNING SECTION

- Good afternoon. My name is Chuck Hollowell. I am an attorney with the law firm Nelson Mullins Riley & Scarborough, L.L.P. I am speaking today on behalf of Forsyth Medical Center.
- Forsyth Medical Center submitted a comment on the Proposed 2008 State Medical Facilities Plan ("SMFP") at the July 20, 2007 public hearing.
- Today's remarks are made in support of this comment by Forsyth Medical Center.
- The Proposed 2008 SMFP currently shows a need for one additional fixed PET scanner in HSA II, where Forsyth Medical Center is located.
- This need determination is based on a methodology that sets capacity for a fixed PET scanner at 2,600 procedures per year. A need for an additional PET scanner is recognized when an existing fixed PET scanner is utilized at or above 80% of this capacity – or 2,080 procedures per year.
- The need set forth in the Proposed 2008 SMFP was generated as a result of Forsyth Medical Center's utilization of its existing PET scanner, which was at approximately 93% of capacity.
- There is some concern that there may be an attempt to change the methodology for projecting the need for fixed PET scanners at this late date in the development of the 2008 SMFP.
- As far as Forsyth Medical Center is aware, no formal petition has been submitted to the SHCC to make such a change.
- Instead, Dr. Edward Coleman from Duke University Medical Center submitted a letter in May to Mr. Elkins in the Planning Section suggesting that the need for an additional PET scanner should be recognized when an existing fixed PET scanner is performing 2,500 procedures per year – as opposed to 2,080 procedures as set forth in the Proposed 2008 SMFP.
- Based on this letter, there was discussion at the May 16 meeting of the SHCC's Technology and Equipment Committee that this threshold should be raised.
- Subsequently, a "PET Scanner Discussion Group Meeting" has been scheduled for August 15, 2007.
- Forsyth Medical Center is concerned that there may be an attempt to change the need methodology for PET scanners after the public hearing process for the Proposed 2008 SMFP has ended.
- Forsyth Medical Center believes this would be improper.
- The 2007 SMFP sets forth very clear procedures governing petitions to change the SMFP's need methodologies. The 2007 SMFP states that any petitions proposing a

revision to the need methodologies must be submitted to the Planning staff as early in the year as possible, and no later than March 7, 2007. It states that these types of changes will need to be considered in the first four months of the calendar year as the Proposed SMFP is being developed.

- Thus, the 2007 SMFP makes it very clear that any proposal to change a need methodology in the SMFP, must be submitted early in the year, so that it can be considered during the first four months of the year. This allows such fundamental changes to be fully considered by the SHCC and incorporated into the Proposed SMFP, which is then made available for review and comment in a timely manner. This allows such fundamental changes to be considered as part of the public hearing process that is taking place at this time.
- In the notice from the Department of Health and Human Services regarding the public hearing process, it states: "The hearings provide the public an opportunity to comment on all aspects of the proposed plan."
- Mr. Fitzgerald is quoted as saying: "Public comment is a critical part of the process that shapes and fine-tunes the State Plan."
- If such a fundamental change in a need methodology is not proposed or considered until *after* the public hearing process has ended, then this deprives the public of the opportunity to comment on such changes.
- It would be directly contrary with the procedures governing the development of the annual SMFP to first consider a proposal affecting a need methodology at an August 15 "PET Discussion Group Meeting" that takes place *after* the final public hearing on August 1.
- Such a change can only be properly considered as part of the preparation of the 2009 SMFP next year.
- If the need methodology for PET is changed at this time, this would likely eliminate the need determination in the 2008 SMFP for an additional fixed PET scanner in HSA II.
- However, there are numerous reasons why this would not be appropriate.
- These issues are discussed in detail in the written comments that Forsyth Medical Center previously submitted regarding this issue at the July 20 public hearing in Greensboro.
- To highlight just a few of these reasons:
  - Table 9K in the Proposed 2008 SMFP shows that Forsyth Medical Center ranks *first* out of 22 facilities in the State with PET scanners in terms of PET scanner utilization, with utilization at approximately 93% of capacity;
  - The Proposed 2008 SMFP recognizes that "the clinical use of PET scanning is increasing rapidly, and the new applications involve the diagnosis of cancer;"
  - It appears likely that other PET codes will be added for reimbursement, such as those for cancer treatment monitoring and re-staging of cancer recurrence; and
  - Table 9G in the Proposed 2008 SMFP shows that Forsyth Medical Center ranks *second* out of 64 facilities in the State providing radiation oncology service in the number of procedures performed.

- Thus, Forsyth Medical Center currently has the highest utilization of its existing PET scanner of any scanner in the State, and this utilization is only expected to increase given the Forsyth Medical Center's robust cancer treatment program and the increasing number of cancer-related PET applications
- For these reasons, as well as those set forth in the materials previously submitted by Forsyth Medical Center, we respectfully request that the SHCC not take any action to change the need methodology for PET at this late date in the development of the 2008 SMFP.
- Any such changes should only be made pursuant to the clear process set forth in the SMFP, which allows for all of these issues to be fully considered during the development of the Proposed SMFP, including as part of the public hearing process.
- Thank you.

JUL 20 2007

Medical Facilities  
Planning Section

**Summary of Speaker Remarks in Support of the FMC  
PET Comment In Support of the Need for One New PET Scanner in  
HSA II in the Proposed 08 State Medical Facilities Plan**

**Comments from Vito Basile, M.D.  
Medical Director of Radiology  
Forsyth Medical Center, Winston-Salem, NC  
And**

**Board-Certified Radiologist, Forsyth Radiological Associates**

- Talked about his previous PET experience at an academic institution, when he was in training at the Cleveland Clinic and PET diagnostics were just in the research stage and not in very widespread use outside the academic setting
- Today, as a body imager who specializes in CT, he really appreciates the value-added diagnostic capabilities that PET offers, beyond what CT diagnostics can provide
- The utility of PET has allowed us to really change the way patients are managed; Dr. Basile has seen this firsthand from his active participation with the Forsyth Regional Cancer Center's regular Tumor Board Conferences where experts in surgery, radiation therapy, pulmonology, hematology/oncology, etc. incorporate PET diagnostic information into diagnosis and treatment planning for cancer patients; the PET diagnostic information is have a beneficial impact on the management of the care and treatment of these patients
- Many of our current PET scanner patients are cancer patients, who are often fragile and in a compromised state of health. Thus, late evening PET diagnostic appointments are not always optimal for them or their caregivers or transportation providers
- Dr. Basile is confident that the PET technology and diagnostics are here to stay and will prove themselves useful in the diagnosis and treatment of many other disease processes and illnesses involving neurology, cardiac, orthopedics, infectious disease
- FMC has not yet begun to utilize the scanner for its widest referral base – our current patient load is primarily for oncology and does not yet include cardiology or neurology patients.

**Comments from Carmine Plott, Ph.D., CHP  
Radiation Safety Officer  
Forsyth Medical Center, Winston-Salem, NC**

- My first job after graduate school was at the University of Tennessee Medical Center at Knoxville and we advertised ourselves as the first clinical PET site in the country. Up to that point, all PET centers were purely research-oriented. I'm proud that I have worked in PET for 20 years and have seen it expand from a research modality to a clinically viable modality that is now the standard of care for oncology patients.
- I don't understand the requirement for PET centers to operate 72 hours per week while CT and MRI operate only 66 hours per week. Perhaps this is due to the time required for a PET

exam which is about 2-1/2 hours. After the patient is injected with the radiopharmaceutical, the patient waits 60 to 90 minutes for the radioactivity to circulate throughout the body. The scan follows and takes up to 30 minutes.

- We rely on a regional radiopharmacy to provide us the FDG. Fluorine-18 is used to make FDG and the half-life is only 110 minutes. We are required to work more hours in PET (than CT or MRI), yet we utilize a material with a very short half-life that is cyclotron produced. It is easier to get doses during normal working hours (8 AM to 5 PM) than it is to get doses late in the day (5 PM to 11 PM). Although the vendor is accommodating, we don't have a limitless supply of FDG.
- We have a good working relationship with the regional FDG vendor and we are confident that they would work with us to increase the amount of FDG provided if FMC were to get a second PET scanner; this vendor already works well with us to get early evening doses of FDG for our PET scans that occur after 5 p.m.
- The current hours of operation for the FMC PET/CT scanner are 6:30 a.m. to 11:00 p.m., Monday – Friday (or over 75 hours per week)

**Comments from Mr. Devi Mecum, RT(R)(CV)  
Radiology Clinical Manager  
Forsyth Medical Center, Winton-Salem, NC**

- As a manager, I serve several customers: the radiologist, the referring physician, and most importantly, the patient. I must also comply with all applicable regulations to ensure the safety of the patient and the employee.
- It is my job to: (a) ensure that the diagnostic images are excellent; (b) to communicate the diagnostic PET information to the FMC Cancer Center as efficiently and effectively as possible; (c) to ensure the safety of the patients and the staff that handle and come in contact with the radioactive radiopharmaceutical that is part of the PET diagnostic study; (d) to help manage capacity, throughput, and access to the PET scanner; and (e) to be certain that PET diagnostics are available to referring physicians who care for cancer patients as well as other referring physicians
- Because of demand, I must exercise "creative scheduling" to accommodate up to 18 patients per day on the single FMC PET/CT scanner.
- The indications for which Medicare (and thus other payors) will reimburse PET scans is continuing to expand and I believe this trend will continue based on the work of the National Oncologic PET Registry (NOPR)
- Private insurance providers generally follow Medicare with regard to PET reimbursement. CMS currently reimburses for only 9 cancers. But the National Oncologic PET Registry is a prime example of Medicare's interest in PET. Once Registry data are collected and analyzed, CMS will likely expand its list to include even more indications – so I expected that the PET/CT scanner at FMC will be flooded with even more requests for PET diagnostic studies.
- We need a second scanner to accommodate the needs of our patients, their referring physicians, and the families.

**Comments from Sharon Murphy, Executive Director  
Derrick L. Davis Forsyth Regional Cancer Center  
Forsyth Medical Center, Winston-Salem, NC**

- Our cancer center at FMC has served, according to the NC Cancer Registry, over 3,000 newly diagnosed cancer patients in recent years
- The group of cancer physician experts associated with our cancer center includes: 11 medical-oncologists, 5 radiation oncologists, 4 gyn oncologists, and 20 \_\_\_\_\_
- The medical oncologists offer local access to cancer care in satellite offices located in towns of Winston-Salem, Kernersville, Lexington, Mt Airy, Statesville, Elkin, and Wilkesboro located in five Triad Region counties (Forsyth, Davidson, Iredell, Surry, and Wilkes)
- The patient base that we care for at the Forsyth Regional Cancer Center continues to grow and PET diagnostic information is now incorporated as part of our standard of care
- The PET Diagnostic information is part of the case presentations at our multi-disciplinary Tumor Board presentations; PET diagnostic information helps us plan for the most effective treatment and increases survivability
- To accommodate this growth our Cancer Center and the adjacent Hematologist-Oncologist Medical Office building is now under expansion, which will add 10-15,000 SF of treatment and support space to better serve our patients, families, and physicians

*File: PETForsythComments08SMFPPublicHrGboroBasilePlottMecumMurphy 07 20 07.doc*